



Republic of San Marino

**San Marino Bioethics Committee**

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*TOWARDS RESPONSIBLE XENO BIOLOGY:  
BIOETHICAL PRINCIPLES FOR THE  
RESEARCH, DEVELOPMENT AND  
GOVERNANCE OF "ORGANISMS WITH  
INVERTED CHIRALITY "*

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**POSITION PAPER OF THE SAN MARINO BIOETHICS COMMITTEE**

**STRATEGIC POLICY PAPER ON BIOSAFETY, THE ETHICS OF "MIRROR LIFE" AND  
PROTECTED INNOVATION**

**APPROVED ON JULY 16, 2026**

## 1. INTRODUCTION: THE BREAKDOWN OF THE BIOLOGICAL UNITY AND THE PROSPECT OF A PARALLEL EVOLUTIONARY LINE

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From its very beginnings, molecular biology has operated within a universal biochemical framework known as *homochirality*. Every living organism on Earth shares the same molecular asymmetry: L-type amino acids for proteins and D-type sugars for nucleic acids. This uniformity represents the common language of the biosphere, the essential prerequisite for metabolism, cellular communication and the stability of ecosystems.

The theoretical transition and the emerging practical feasibility of *Mirror-Image Bacteria* (MB) - mirror-image living systems based on D-amino acids and L-sugars — radically challenge this unity. This perspective suggests that, with scientific development moving in this direction, we would not be faced with a mere genomic modification, but with the rewriting of the alphabet of life and the beginning of a parallel evolutionary line, biologically isolated and evolutionarily disconnected from the natural biosphere<sup>1</sup>.

The San Marino Bioethics Committee, in collaboration with its international partners, notes that the debate is objectively complicated, currently fragmented and not yet sufficiently widespread, and that so far it has focused almost exclusively on biosafety. The aim is to promote a form of governance that does not reject innovation, but which is able to anticipate and guide scientific, industrial and clinical developments before commercial dynamics or illicit practices arise in the absence of a clear framework of values.

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<sup>1</sup> To be more precise, *Mirror-Image Bacteria* (or chirally inverted organisms) have not yet been invented or created in their complete, self-sufficient form; for the time being, they remain a theoretical concept in cutting-edge synthetic biology. The scientific journey that led to the theorisation and development of the individual mirror-image “building blocks” has well-defined historical milestones; however, the real *breakthrough* towards synthetic biology applied to mirror-image microorganisms took place around 2016. Scientists such as Ting Zhu (of Tsinghua University and later Westlake University in China) and the Harvard geneticist George Church have begun to recreate parts of biology’s “central dogma” in a mirror-image form in the laboratory. That year, for example, Ting Zhu’s team synthesised a mirror-image DNA polymerase capable of replicating and transcribing mirror-image DNA (*L-DNA*). Just when the creation of an entire mirror-image bacterium was beginning to move from the realm of science fiction to technical feasibility (estimated to be between 10 and 30 years away), the scientific community put a sudden stop to it. By the end of 2024 (following a famous article on “Science” and a comprehensive *Technical Report* on which nearly 40 scientists from around the world had worked, led by bioengineers such as Kate P. Adamala and immunologists/ecologists), the very same scientists who had been studying mirror life decided to suspend their work. They realised that a mirror-image bacterium capable of replicating in the wild would be invisible to predators and viruses, posing a potential uncontrollable ecological threat.

## 2. FROM A STATIC PRECAUTION TO "PROTECTED RECONNAISSANCE": A REFORMULATION OF THE "PRECAUTIONARY PRINCIPLE"

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History shows that with major technological breakthroughs—from nuclear energy to gene editing—fragmenting knowledge and confining early experiments to laboratories makes rapid expansion incredibly difficult to govern. This creates a very real risk of losing control over future developments.

Also, regarding *inverted chirality*, there is a very real and pressing possibility that research may be carried out outside the scope of official regulatory oversight, driven by a variety of competitive or geopolitical interests.

On the other hand, regarding progress as an unstoppable force risks conflating what is technically feasible with what is presumed to be inevitable: a logical and deterministic conflation that ethics has a firm duty to challenge.

Historically, a complex interplay emerges between scientific progress and the timing of moral reflection. The latter, which by its very nature involves a more measured and gradual progression, has at times unintentionally slowed things down, coming across almost as an obstacle to progress itself. Today, Mirror Biology poses an unprecedented challenge: the critical issues surrounding the regulation and governance of such a rapidly expanding field give rise to risks that existing control systems struggle to contain. In the face of this vulnerability in surveillance systems, the only responsible answer is a "*Protected reconnaissance*", which treats safety and risk mitigation as an absolute prerequisite for any scientific progress.

To better clarify the concept, the traditional *Precautionary Principle* can no longer be understood as a mere static prohibition, a bureaucratic obstacle or a barrier to innovation that would risk causing the democratic scientific community to lose control of progress, potentially leading to unlawful practices. It might be more appropriate today to propose a *dynamic reformulation* of it. There can be no doubt that science should advance; accordingly, the exceptional scientific potential of Mirror Biology should not be stifled but rather pursued with due caution.

At the same time, scientific progress should ideally advance by exploring and placing at the forefront all the tools, monitoring systems and protocols designed to neutralise and protect against adverse events. It should therefore be made clear – and hoped – that research and development of chirally inverted systems should only move forward if they are preceded by the implementation of innovative containment measures, thereby transforming uncertainty into a field of active vigilance and incremental ethical design. Far from a green light for biological proliferation, this opening is a call for strict and exclusive caution, in line with the World Health Organization's adaptive approach: allowing controlled theoretical and molecular exploration for the sole purpose of developing the countermeasures necessary for global biosecurity. Clearly, what marks a break with the past is the new role assigned to ethics, which is called upon to act as an *ethical vanguard* for safeguarding scientific progress. Its mandate is not an abstract prohibition that would leave the world defenseless against external forces, but a binding priority: safety engineering must take precedence over life engineering. Field testing of mirror bacteria cannot be considered a current option, and any physical manipulation may only be authorized in an environment already fully prepared and protected by proven bio-containment protocols, towards which research should be directed and promoted at a preliminary stage. This strategy — which we might summarise as the imperative to *build the rescue system before building the structure that will house the experiment* — responds to the absolute necessity of safeguarding what already exists, so that the pursuit of the new — given the promising potential it appears to offer — never becomes an irreversible threat to the biosphere.

### 3. THE EXTRAORDINARY POTENTIAL OF INVERTED CHIRALITY

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The CSB aligns with the broad global scientific consensus that creating an autonomous, replicating "Mirror Life" organism offers few predictable benefits compared to its immense systemic risks. Ethical reflection must therefore draw a sharp distinction: while we must reject the goal of creating a self-sufficient Mirror Biology, we should explore specific, isolated, and cell-free molecular applications. It should indeed be clarified that, in light of a rigorous ethical analysis, the scientific finding that individual Mirror-Image polymers are biochemically stable against the degradation mechanisms of the conventional biosphere need not be interpreted solely as a risk factor, but may also represent a potential key to unprecedented biotechnological solutions.

It should first be noted that, in light of a rigorous ethical analysis, the scientific finding that Mirror-Image Bacteria are biochemically stable against the degradation mechanisms of the natural biosphere should not be interpreted solely as a risk factor, but also as a potential basis for unprecedented biotechnological solutions.

Even at first glance, the concept of "resistance to enzymatic degradation" promises to revolutionize the field of pharmacokinetics. Indeed, the development of Mirror-Image peptides, nucleic acids and enzymes may enable the design of drugs and therapeutic devices with an exceptionally long biological half-life in the host organism, reducing the frequency of administration of drugs and offering new and more stable diagnostic approaches.

Furthermore, it should be noted that, due to their incompatibility with natural hydrolases, proteases and nucleases, Mirror-Image biomolecules are highly resistant to environmental and enzymatic degradation. From a more forward-looking perspective, this structural stability opens up the possibility of using Mirror-Image systems as genuine long-term biological archives. MBs could, in other words, act as information carriers capable of preserving historical data, complex codes or fundamental genetic instructions over geological timescales or in view of the most profound planetary changes, surviving catastrophes that would wipe out current conventional digital or biological storage media. This shifts the focus of synthetic biology from short-term utilitarianism to the preservation and safeguarding of our knowledge heritage over the long term.

Finally, systemic biochemical incompatibility — that is, the inability to exchange genetic material via horizontal transfer or to metabolise natural substrates — paradoxically provides a special intrinsic "safety barrier". Indeed, if guided by strict criteria of impermeability and absolute parallelism, this separation of biological alphabets can create an "ethical buffer zone" within confined systems, allowing high-risk models to be tested without immediately interfering with the Earth's evolutionary processes.

## 4. ETHICAL, ONTOLOGICAL AND REGULATORY RISK PROFILES

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However, taking on this technological challenge requires a detailed mapping of the systemic risks that the *protected reconnaissance* must be able to neutralise. First of all, a necessary *redefinition of the concept of "Life"* seems provocative, if only because of the obvious regulatory gaps that result from it. Mirror-Image Bacteria challenge the traditional definitions of a "living system", which have historically been based on natural evolutionary lineage. There is therefore a real risk that industrial entities or multinational corporations might exploit the ontological ambiguity of Mirror-Image Bacteria, arguing that they do not meet the traditional criteria for a "living organism" or a "GMO", in order to circumvent existing legislation on biosafety and environmental law. Such a regulatory gap could lead to unregulated commercialization, fatally undermining public trust in science.

Another critical issue is the erosion of the concept of *ecological unity and uniqueness*. The Earth's biosphere possesses a value linked to its specific evolutionary history and its shared biochemistry; this value is intrinsic, moral and even aesthetic (consider the value of "beauty" inherent in nature). Although MBs are created in isolation, their introduction leads to a conceptual and ecological fragmentation of the biosphere. The idea that humanity can create an alternative and unassailable biochemical heritage risks fuelling excessive anthropocentric ambition and undermining cultural and scientific efforts to conserve "traditional" species and natural ecosystems, so to speak, which are mistakenly perceived as no longer unique or irreplaceable. In this regard, the Position Paper embraces the extreme caution voiced by the signatories of "*The Spirit of Asilomar*"<sup>2</sup>: openness to understanding inverted chirality must never be interpreted as an endorsement of an autonomous "Second Genesis" on Earth. Instead, it remains strictly bound to the absolute protection of our planet's sole native biosphere.

Finally, we might even see a gradual *normalisation of the technical and scientific progress in hetero-chirality*, to the extent that it could pave the way for a possible escalation of basic standards. Indeed, the gradual acceptance and inevitable commercial success of the first Mirror-Image Microbial forms could trigger a shift in ethical boundaries. What appears radical today could be normalised, thereby reducing social and critical resistance to far more complex and potentially irreversible interventions, such as the anthropic design of entire synthetic macroscopic ecosystems with inverted chirality<sup>3</sup>.

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<sup>2</sup> Abbott, Z., Adamala, K., Esvelt, K., et al. (2025). *The Spirit of Asilomar and the Future of Biotechnology: Entreaty on the Risks of Mirror Life*. Summit Report and Global Appeal, Asilomar, California.

<sup>3</sup> The recent publication of the WHO's *Global Guidance Framework* now requires a strict distinction to be drawn between *Mirror Biology* (acellular molecular technologies such as hydrogels and nanopores) and *Mirror Life* (self-transmissible living systems). Since advances in chemical-enzymatic synthesis (*Mirror Biology*) already meet a large proportion of current bioproduction needs, the engineering of actual replicating "Mirror-Image organisms" (*Mirror Life*) appears to be a redundant and extremely high-risk biotechnological effort.

## 5. PREDICTIVE INFORMATICS AT THE FOREFRONT OF BIOSAFETY: AI MODELS AND ACTIVE *IN SILICO* CONTAINMENT

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To ensure that research is not held back by static prohibitionism but instead progresses whilst being safeguarded by its own protections, the Committee is promoting the establishment of a new and independent field of scientific and bioinformatics research, entirely dedicated to the pre-validation of safety systems. Before any *in vitro* or *in vivo* experimentation on vital systems with inverted chirality begins, science has a duty to investigate the mechanisms for defence and risk neutralization. To achieve this, the scientific community can now benefit from an extraordinary and providential historical convergence: indeed, the development of Mirror Biotechnologies coincides with the emergence of Artificial Intelligence (AI), a tool that is fortuitously well-suited to translating this ethical urgency into a concrete and systematic protective simulation framework.

To this end, on the basis of this historical convergence, strategic standards and minimum protection requirements can be defined. Examples of this might include hypothetical "Virtual simulation platforms and predictive scenarios". In essence, research into Mirror Biology can be preceded by advanced computational models capable of simulating hetero-chiral biochemical interactions *in silico*. These predictive algorithms would be responsible for generating complex virtual scenarios to anticipate mutations, exceptionally restrictive escape rates and any potential metabolic escape routes, whilst maintaining the current biosphere in a state of absolute and intrinsic safety.

Another example might be the creation of "ecosystem digital twins" – that is, the development of digital models of microbial ecosystems that are entirely similar to the originals – in order to virtually test the impact of introducing hypothetical Mirror-Image Bacteria. This "digital buffer zone" will make it possible to map ecological risk profiles and validate biochemical impermeability prior to any physical molecular synthesis.

Furthermore, a form of "computational engineering of decontamination protocols" could also be developed. Having noted the ineffectiveness of standard biological and enzymatic agents on mirror life, Artificial Intelligence could be used to design "Mirror homologous" synthetic molecules and enzymatic vectors capable of bringing about targeted, aggressive and radical chemical destruction, whilst ensuring the existence of an "antidote" or a reliable neutralization protocol prior to the organism's emergence.

Finally, it would be desirable to establish standardised BSL-4 laboratories<sup>4</sup> in order to ensure effective "physical containment". Consequently, once predictive models and *in silico* simulations have validated the effectiveness of genetic firewalls and synthetic metabolic dependencies, any subsequent synthesis and physical manipulation of living Mirror-Image microorganisms will be strictly confined to facilities with the highest level of biological containment (BSL-4), in accordance with the chemical and physical protocols previously identified by the simulations.

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<sup>4</sup> *Biosafety Level 4*: this is the highest level of biosafety required for laboratories handling extremely hazardous biological agents.

## 6. CLINICAL TRIALS, PREDICTIVE PHARMACOVIGILANCE AND THE PROTECTION OF RESEARCH SUBJECTS

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In light of the above, a further and decisive step forward is required, capable of combining algorithmic biosafety with the ethical imperative to direct research towards the ultimate benefit and care of Humanity.

The future clinical translation of the extraordinary therapeutic potential of hypothetical "Mirror drugs" already requires us to move beyond traditional trial protocols, integrating advanced computational systems from the outset to protect patients. Since *in vitro* behaviour may not reflect the complex *in vivo* kinetics, and given that L-nucleic acids and D-proteins cannot be processed by normal human metabolic pathways, there is a real risk of chronic accumulation and entirely unprecedented immune responses. Consequently, future regulations will require clinical enrolment to be strictly preceded by Artificial Intelligence–guided *in silico* pharmacokinetic simulations.

Subsequently, clinical trial phases will need to include lifelong active pharmacovigilance channels, supported by predictive algorithms capable of detecting patterns of silent toxicity or tissue accumulation at an early stage.

In this context, informed consent takes on critical importance: patients enrolled in the trial must be given an explicit and detailed explanation of the radical otherness of the molecule being administered. The patient must be clearly informed that the therapeutic agent is biocatalytically foreign to human biology and that, in the event of unforeseeable adverse reactions, its removal or neutralisation will depend on cutting-edge bioinformatic and molecular protocols and countermeasures, which are not always supported or permitted by current standard medical and therapeutic practices.

## 7. CROSS-BORDER GOVERNANCE, OPEN SCIENCE AND "DYNAMIC REGULATORY ADAPTATION"

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Finally, one last clarification appears necessary. Since microorganisms and synthetic molecules know no geographical or political boundaries, and the vectors through which they spread pose a global biological challenge, the regulatory response must be equally global, transparent and shared.

The Committee reiterates its firm rejection of "regulatory havens" or free zones in which to conduct experiments without international oversight. The proposal is to establish an "International Digital Surveillance Network" that uses Artificial Intelligence, governed by internationally recognized regulatory instruments, to monitor sequencing data and global research activities, promptly detecting anomalies or attempts at clandestine synthesis conducted outside shared ethical and normative frameworks. This digital monitoring system is the essential prerequisite for genuine "dynamic regulatory adaptation": a governance model capable of fine-tuning and updating authorisation protocols in real time, keeping pace with scientific discoveries.

From this perspective, the governance of Mirror Biology cannot be limited to simply extending the current regulations. The absolute biological separation imposed by chiral orthogonality requires an entirely new international regulatory framework, based on a genuine "protection policy". In this model, the strictness of public oversight must increase in proportion to two critical factors: the complexity of the system and its proximity to the ability to replicate itself autonomously.

Rather than merely managing the damage *ex post*, this framework should be designed as a flexible, multi-tiered authorisation system. Precautionary checks and restrictions should be implemented in accordance with the biological complexity or potential danger posed by the organism, so as to accompany the research step by step and strictly before any theoretical concept is turned into physical reality.

The inherent complexity of this multi-layered approach suggests that the establishment of an *International Supervisory Body* specifically dedicated to the biosafety of inverted chirality should be promoted as a long-term strategic objective. Such a permanent supranational authority – conceived as a neutral, third-party forum for scientific and bioethical cooperation – would be essential for centralising global research registries, coordinating cross-border impact assessments and monitoring compliance with agreed ethical limits, thereby providing States with a shared framework of safeguards and a formal defence against any risk of clandestine proliferation.

That is not all: in response to the push towards the monopolistic commodification of this "Second Genesis", the San Marino Bioethics Committee argues that fundamental knowledge of Mirror Biology must strictly comply with the principles of *Open Science*. Chemical synthesis protocols, chiral replication mechanisms and, above all, predictive safety models and neutralisation algorithms must not be subject to exclusive commercial patents. Access to computational protective technologies must be guaranteed as a global public good, preventing technological disparities among nations from translating into an unacceptable biosafety gap.

## 8. FINAL RECOMMENDATIONS AND STRATEGIC GUIDELINES: THE DUTY TO ANTICIPATE

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The San Marino Bioethics Committee concludes this Position Paper by reaffirming that the success and maturity of a technological civilisation are not measured by the speed with which humanity is able to push forward the boundaries of what is possible, but by the wisdom, foresight and structural care with which it decides *how, when and under what conditions* those boundaries should be crossed.

The introduction of Artificial Intelligence, in the context of one of its hypothetical applications as described, is not merely a technical tool, but an epoch-making ethical responsibility: it offers us, for the first time in the history of science, the opportunity to explore the unknown and neutralise its dangers even before they manifest themselves in the physical world.

The San Marino Bioethics Committee therefore aims to serve as a permanent platform for interdisciplinary dialogue between science, philosophy, bioinformatics and ethics, urging the Ethics Committees of the various partner States and international organisations to act as promoters and advocates of an informed, transparent public debate based on sound scientific principles. The hope is that the promise of inverted chirality science will not be blocked, especially where it can generate innovative molecular platforms to protect health and life. However, its advancement must be preceded, escorted, and continuously validated by the proactive deployment of its own simulations, defenses, public awareness, and a total containment framework that honors the highest standards of international precaution.

Accepting this challenge means looking to the future with confident determination, in the belief that the true light of progress lies not in the speed of discovery, but in humanity's ability to shed light on the path even before embarking on it.

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## EXPLANATORY NOTE TO THE POSITION PAPER

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This Position Paper stems from the pressing and unavoidable need to proactively address—from an ethical, regulatory, and philosophical standpoint—the developments of one of the most radical technological transitions in the history of science: the emergence of Mirror-Image Biology. By disrupting the universal biochemical boundaries of homochirality, which has unified and stabilized the terrestrial biosphere for billions of years, the creation of "Mirror-Image Organisms" does not merely represent a genomic modification, but rather the inauguration of a parallel and biologically isolated evolutionary lineage.

The formal and substantive reasons that prompted the Sammarinese Committee of Bioethics to conceive this strategic policy document are structured across three fundamental dimensions:

- *Overcoming the Regulatory and Ontological Vacuum*: Current classical definitions of "living systems" or "GMOs" are modeled upon natural evolutionary descent. There is a concrete risk that this regulatory vacuum could be exploited by industrial actors to bypass existing biosafety laws, leading to unregulated commercialization and undermining public trust.
- *A Dynamic Reformulation of the Precautionary Principle*: Historically, moral reflection has been perceived as an obstacle or a belated brake on scientific advancement. In the face of the potential irreversibility of mirror-image life, traditional "static" precaution (consisting of mere bureaucratic prohibitions) proves vulnerable. This document introduces the paradigm of "*Protected reconnaissance*", a binding order of precedence wherein safety engineering and biocontainment must categorically precede life-engineering. Bioethics thus assumes an authentically innovative function, positioning itself as the vanguard and the very precondition of scientific action, establishing the principle that the evaluation of limits must precede the exercise of technological power.
- *The Ethical Exploitation of Therapeutic Potential*: This document is not intended to inhibit innovation, but to guide it toward areas of undisputed biomedical utility. The extraordinary biochemical stability of mirror-image biomolecules promises a revolution in pharmacokinetics—through the development of innovative, life-saving molecular elements and platforms with extended half-lives—as well as in data storage over geological timescales. The underlying rationale is to define the minimum requirements to ensure that these clinical promises advance safely and exclusively within acellular, isolated, and controlled environments.

By leveraging the providential historical convergence of synthetic biology and the maturity of Artificial Intelligence, appropriately governed by internationally recognized regulatory instruments, this text aims to serve as a global strategic platform. Indeed, the integration of AI into this field of hypothetical application is not merely a technical aid, but an epochal ethical responsibility: it offers us, for the first time in the history of science, the ability to explore the unknown and neutralize its hazards *in silico* before they ever manifest in the physical world.

In summary, the ultimate purpose of this document is to fulfill *the duty of anticipation*: to demonstrate that the success of a technological civilization is not measured by the speed of its discoveries, but by its far-sighted capacity to illuminate the path ahead, embracing the highest standards of global safety and establishing safeguarding systems before venturing into the unknown. In this context of *anticipation*, and prior to the enactment of legal norms, it is the duty of Bioethics to outline the principles for protecting a biosphere already rendered fragile by the widespread deployment of poorly governed technological innovations.