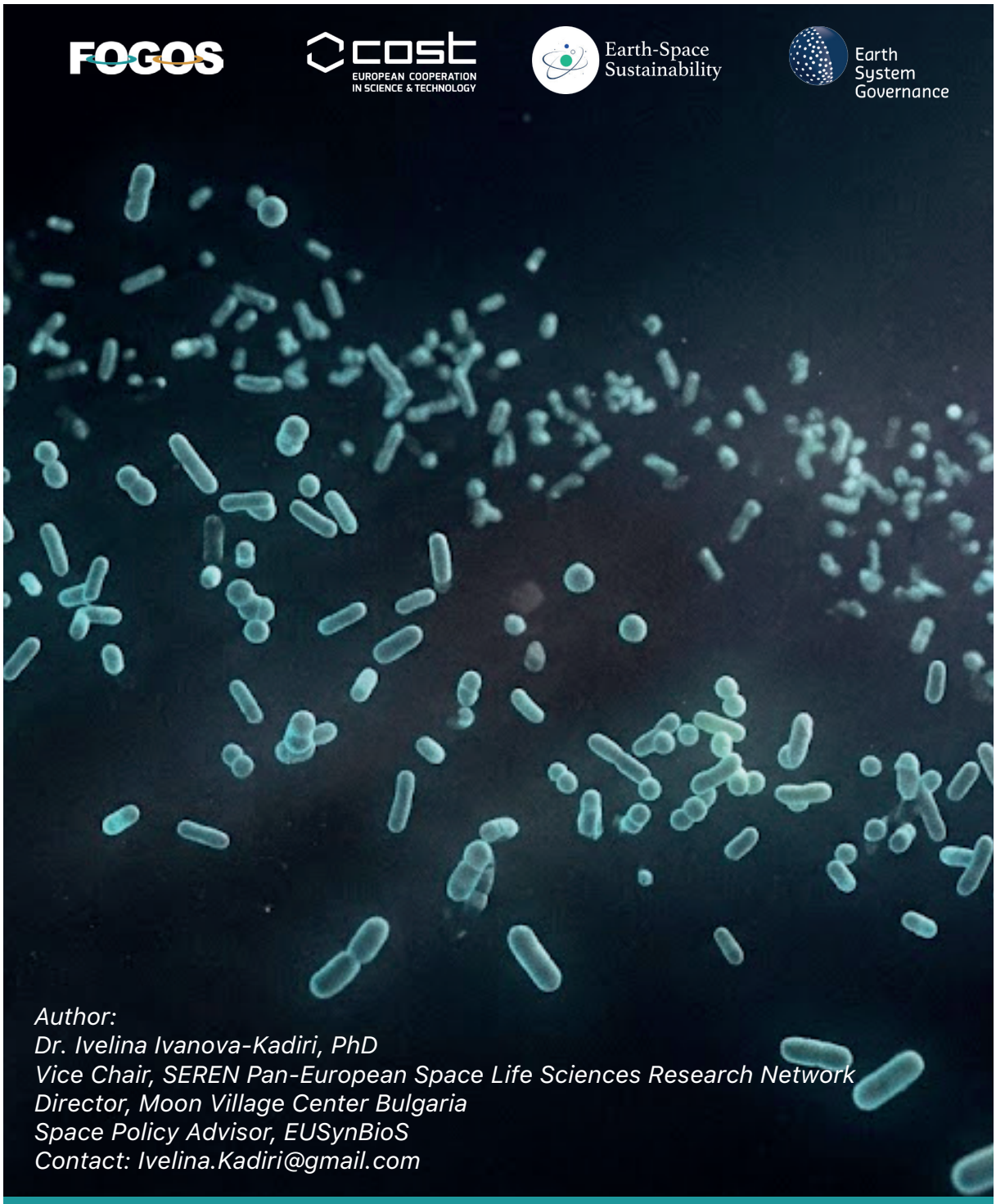


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Aligning the EU Space Act and Biotech Act on Biosafety and Genomic Data Governance

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KEY MESSAGES

The proposed EU Space Act (COM(2025) 335) addresses resilience exclusively through cybersecurity (Articles 75–95). It contains no biosafety requirements for operators conducting biological research in orbit, despite peer-reviewed evidence that microgravity predictably generates organisms with altered virulence and antibiotic resistance profiles.

The proposed EU Biotech Act (COM(2025) 1022), tabled on 16 December 2025 to strengthen the Union's biotechnology and biomanufacturing sectors across seven pillars, was developed without cross-reference to the proposed EU Space Act (COM(2025) 335), tabled on 25 June 2025. The Biotech Act's Foresight Panel for Emerging Health Innovation (Pillar 5) and Advisory Group on Biosecurity (Pillar 6), the EU's most advanced anticipatory governance mechanisms, do not expressly cover space life sciences.

The European Health Data Space (Regulation (EU) 2025/327) delays genomic and omic secondary use provisions until 26 March 2031 (Article 105), creating a six-year governance gap for the data categories most generated by space life sciences research.

Open access to space omics data, exemplified by the Space Omics and Medical Atlas released in June 2024, currently outpaces binding regulatory governance: existing safeguards operate through mission-level informed consent and institutional review rather than a harmonised framework for retention, secondary use, cross-border transfer, or benefit-sharing of astronaut genetic data.

1. Context

In plain terms, the problem is this: space-based biological and genetic research has moved well ahead of the rules meant to govern it. Microgravity can make bacteria more dangerous, yet no law requires space operators to guard against that risk. Two major EU proposals, the Space Act and the Biotech Act, address related risks in parallel but were drafted without reference to each other, so neither closes this specific gap. A separate EU data protection framework will not even begin to cover this kind of genetic data until 2031. Each of these gaps can still be closed, but only within the current legislative process, which is why this brief proposes six targeted recommendations below.

The two legislative instruments addressed in this brief, the EU Space Act (COM(2025) 335, proposed 25 June 2025) and the EU Biotech Act (COM(2025) 1022, proposed 16 December 2025), are advancing through the European Parliament in parallel. Both are under active negotiation as of mid-2026. The Parliament's Industry, Research and Energy Committee (ITRE) is drafting its report on the Space Act, and its Environment, Public Health and Food Safety Committee (ENVI) is preparing its opinion on the Biotech Act. These are the appropriate procedural moments for the amendments proposed below.

The commercial space life sciences sector is not hypothetical. In June 2024, researchers published the Space Omics and Medical Atlas (SOMA), the largest public collection to date of astronauts' genetic and health data, drawing on five missions and over one hundred institutions in more than twenty-five countries [1,2]. Everyone involved agreed to share this data voluntarily, in the absence of any legal requirement specifically obliging them to do so. Because outer space is not explicitly addressed within the general legal instruments that might otherwise apply, retention, access, and downstream use of this data fall into a potential governance gap, one that the sensitivity of genetic and health information and the risks at stake arguably warrant closing through legislation targeting this research specifically.

2. Biosafety Gap in the EU Space Act's Resilience Framework

2.1 Omission

The EU Space Act's resilience framework (Articles 75–95) is structured principally around cybersecurity threats, supplementing the EU's existing cybersecurity rules under Directive (EU) 2022/2555 on measures for a high common level of cybersecurity across the Union (the NIS2 Directive) with space-specific lex specialis provisions. This approach is appropriate for cyber risk. However, the resilience pillar contains no provisions on biological risks arising from space activities: no biosafety requirements for operators conducting microbial or synthetic biology research in orbit, no containment standards, and no obligations governing the return of biological samples that may have acquired novel characteristics during spaceflight.

2.2 Evidence Base

Peer-reviewed research on multiple missions to the International Space Station (ISS) points to a consistent pattern: bacteria become more dangerous in microgravity. In the most studied case, Salmonella, a common cause of food poisoning, became significantly better at causing disease in mice after being grown in simulated microgravity, an effect later confirmed under real spaceflight conditions [3,4]. Similar findings have been reported for other bacterial species aboard the ISS: increased lethality in one case, and genetic divergence from Earth-based strains linked to disease-causing potential in another [5,6].

This evidence base has identifiable limitations: the number of independent studies is small, the organisms and model systems vary, and virulence persistence beyond microgravity is not uniformly demonstrated. This brief does not assert the science is settled. The argument is that the consistent directionality of findings, towards increased virulence under microgravity, combined with the severity of the potential consequence, satisfies the threshold for precautionary regulatory action under Article 191(2) of the Treaty on the Functioning of the European Union (TFEU) and the Commission's Communication on the Precautionary Principle (COM(2000) 1).

2.3 Structural Parallel

The Act's own internal logic supports extending resilience to biosafety. Just as the Act recognises that general cybersecurity instruments are insufficient for the specific risk profile of space infrastructure, general biosafety instruments are insufficient for the specific risk profile of orbital microbiology. No binding international instrument fills this gap. The Committee on Space Research (COSPAR), the body that sets planetary protection standards, has no

power to bind commercial operators. The Cartagena Protocol, the main international treaty on biosafety, is not a workable alternative: the United States and Russia are not parties, and even for states that are, including EU Member States and China, it is doubtful that biological research conducted in orbit constitutes 'transboundary movement' of living modified organisms within the meaning of Article 4, leaving the Protocol without a clear mandate over the activity in question. In the absence of a workable global instrument, EU action through its own authorisation regime is not merely appropriate but necessary.

3. Foresight Panel Gap in the EU Biotech Act

3.1 Anticipatory Governance Mechanism

The EU Biotech Act establishes two mechanisms relevant here: a Foresight Panel for Emerging Health Innovation (Pillar 5) that provides horizon-scanning, and an Advisory Group on Biosecurity (Pillar 6, Article 53) that monitors emerging biosecurity risks. Both are the EU's most advanced anticipatory governance tools.

Their limitation is scope: the Act covers health biotechnology "in the human medical, veterinary, pharmaceutical and phytosanitary areas," a definition that does not expressly include space life sciences. This is a drafting gap, not a principled exclusion, and it is untenable now that orbital biology is no longer the sole preserve of governmental agencies.

3.2 Dual-Use Dimension

The Biotech Act requires screening of desktop DNA-synthesis machines, equipment that lets a user manufacture custom genetic material (Article 45), because unscreened output could be used to create dangerous genetic sequences. The same machines are now being miniaturised and adapted for use in orbit. Techniques under consideration for keeping astronauts healthy on long missions, including gene-based approaches to radiation resistance and metabolic adaptation [7], pose the same dual-use risk the Act was designed to address on the ground. Since these are health biotechnology applications, they fall within the Act's subject matter regardless of where they are performed. The Foresight Panel's mandate should follow.

4. Genomic Data Governance Gap

The biological research examined above, spanning microgravity-altered pathogens and orbital synthetic biology, also generates substantial volumes of astronaut genomic and health data, and the framework governing that data lags in a comparable way. The European Health Data Space (Regulation (EU) 2025/327), in force from 26 March 2025, creates the most sophisticated health data governance framework globally. EU-established operators collecting genomic, omic, or biomedical data from spaceflight participants likely qualify as "health data holders" subject to mandatory secondary use sharing under the HealthData@EU permit framework.

However, the EHDS delays genomic and omic secondary use provisions until 26 March 2031 (Article 105), a six-year gap for exactly the data categories most generated by space life sciences research. The EHDS does not apply to non-EU-established data holders absent reciprocal arrangements, compounding the gap.

This gap is made worse by three problems specific to the space context. **Consent may not be meaningful.** Astronauts depend on their agency or employer for their career and, in some respects, their safety, a position of dependency that can compromise how freely they can decline to give consent (a problem the EU's data protection law, the General Data Protection Regulation (GDPR), acknowledges in principle at Recital 43, without resolving it for spaceflight). Cosmic radiation also causes genetic mutations during the mission itself, so genetic data collected before launch may no longer accurately describe the astronaut's genome afterwards. Consent given before a mission cannot simply be assumed to cover the data the mission actually generates.

There is no requirement to share the benefits of astronaut data. Commercial firms can freely use open-access repositories such as SOMA to train proprietary algorithms and develop products, with no obligation to share benefits with the astronauts or missions that generated the data. UNESCO's 2003 International Declaration on Human Genetic Data contains a non-binding benefit-sharing principle (Article 19), but it was not designed for orbital research and has no legal force.

Standard anonymisation does not work on a population this small. Fewer than seven hundred people have ever flown to space, and their identities and mission histories are largely public. Removing a name from a genetic dataset drawn from so small and well-documented a population does not reliably prevent re-identification, a problem current data protection rules do not address.

5. Policy Recommendations

This brief proposes six recommendations targeting the current legislative cycle. Each is independently justified and should be pursued regardless of the others' progress. Their combined effect is greater than the sum of their parts.

R1 Amend the EU Space Act: biosafety as an authorisation condition

Require that operators conducting biological research in orbit, as a condition of authorisation by the EU Agency for the Space Programme (EUSPA), demonstrate compliance with biosafety standards developed through mandatory coordination between EUSPA, the European Centre for Disease Prevention and Control (ECDC), and the European Medicines Agency (EMA). This coordination mechanism should establish containment standards appropriate to the orbital context, dual-use risk assessment requirements, and mandatory protocols governing the return, quarantine, and analysis of biological samples. The precedent is the Act's existing cybersecurity provisions.

R2 Amend the EU Biotech Act: extend the Foresight Panel's mandate to space life sciences

Amend the provision establishing the Foresight Panel's scope to include space life sciences and orbital synthetic biology explicitly. Require the Panel to produce an initial biosecurity risk assessment of microgravity-altered microbial behaviour within twenty-four months of the Act's entry into force. This timeline reflects the minimum period for rigorous evidence review.

R3 Amend the EU Biotech Act: adapt biosecurity screening to orbital deployment

Extend the scope of biosecurity screening requirements under Article 45 to include benchtop nucleic acid synthesis equipment that is miniaturised, ruggedised, or otherwise designed or adapted for deployment in the orbital environment.

R4 Establish inter-agency coordination between the Biotech Act and the Space Act

Include an explicit provision in the EU Biotech Act requiring the Foresight Panel (Pillar 5) and the Advisory Group on Biosecurity (Pillar 6) to coordinate with EUSPA, establishing a formal channel for horizon-scanning findings and biosecurity risk assessments relevant to orbital research to inform EUSPA's authorisation standards under the EU Space Act.

R5 Establish a Space Health Data Governance Architecture

Create a dedicated legal framework under the EU Space Act to bring spaceflight-generated omic and genomic data within a permit-based secondary use framework before the EHDS Article 105 deadline of 2031. This framework should be administered by a Space Health Data Access Body established as a functional unit of EUSPA, applying EHDS-equivalent standards adapted for orbital data collection environments.

R6 Establish binding benefit-sharing and data stewardship for space omics

Introduce binding benefit-sharing requirements for commercial exploitation of astronaut genomic data, drawing on the principle in UNESCO 2003 Article 19. Require post-mission genomic consent supplements acknowledging radiation-induced mutation. Mandate longitudinal data stewardship frameworks for astronaut omic datasets, with the International Standards for Space Omics Processing (ISSOP) consortium providing the scientific standardisation infrastructure.

6. Legislative Window

Both instruments are under active negotiation. Neither committee should defer action on the instrument within its competence on the basis that the other committee has not yet acted. The optimal outcome is adoption of both sets of amendments within the current legislative cycle, but each set is independently justified.

Researchers working within FOGOS, a network spanning 40+ countries with established links to COSPAR, the International Astronautical Federation, and the Secure World Foundation, are well placed to contribute the science–policy interface both processes require.

A related track, the Commission's Call for Evidence on Biotech Act II (closed 10 June 2026), addresses industrial biomanufacturing issues that properly belong in that second instrument. The biosafety, biosecurity, and genomic data governance issues in this brief do not: they fall within the health dimension already governed by Biotech Act I and must be resolved now. Deferral to Biotech Act II would leave these gaps open indefinitely.

The European Parliament has the opportunity, within the current legislative cycle, to establish this coordination architecture before commercial space biology expands beyond the point at which proactive governance remains feasible.

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