EANM Suggestions for Amendments

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)

Provision	Commission Proposal	EANM Amendment Suggestion (in bold)	In EANM Paper
Recital 12a new		**For certain categories of health biotechnology characterized by complex or overlapping regulatory frameworks, specific manufacturing requirements, or time-sensitive distribution and clinical use, including radiopharmaceutical and theranostic products, appropriate account should be taken of their particular characteristics and of the applicable sectoral regulatory requirements when implementing the Strategic Projects framework and related support measures under this Regulation.**	Section 1
Recital 21	Recognizing the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks, building on analyses done in the context of existing Union initiatives such as the European Health Data Space , the Apply AI Strategy, the Data Union Strategy, the AI Continent Action Plan and the European Strategy for AI in Science. (…)	Recognizing the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector, **as well as relevant gaps in digital and AI literacy across the biotechnology workforce,** and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks, building on analyses done in the context of existing Union initiatives such as the European Health Data Space , the Apply AI Strategy, the Data Union Strategy, the AI Continent Action Plan and the European Strategy for AI in Science. (…)	Section 2.c)

Recital 65	(…) These infrastructures should support the development of biotechnology applications where the use of AI has the potential to accelerate progress, in particular in health-related areas such as advanced therapies, where AI can improve efficacy and safety — for example through optimized CRISPR site prediction, tumor antigen identification, sequence engineering, delivery-vehicle design, or the matching of diverse patient cancer-cell variants with CAR-T cell types.	(…) These infrastructures should support the development of biotechnology applications where the use of AI has the potential to accelerate progress, in particular in health-related areas such as advanced therapies, where AI can improve efficacy and safety — for example through optimized CRISPR site prediction, tumor antigen identification, sequence engineering, delivery-vehicle design, **quantitative imaging and dosimetry optimization,** or the matching of diverse patient cancer-cell variants with CAR-T cell types.	Section 5. b)
Recital 127	(…) Strengthening reliance on the reporting Member State's assessment would reduce duplication of work and allow Member States and sponsors to allocate resources more effectively, while ensuring high level of protection of subjects and the robustness of data.	(…) Strengthening reliance on the reporting Member State's assessment would reduce duplication of work and allow Member States and sponsors to allocate resources more effectively, while ensuring high level of protection of subjects and the robustness of data. **For categories of clinical trials involving technologies subject to additional sectoral regulatory requirements, including radiopharmaceutical clinical trials, effective coordination between clinical trial authorities and other competent authorities, such as radiation protection authorities where relevant, may further support the efficient conduct of multinational clinical trials while maintaining high standards of subject protection and safety.**	Section 6.d)
Recital 138a new		**The involvement of radiopharmaceuticals in a clinical trial should not in preclude the categorisation of that trial as a minimal-intervention or low-intervention clinical trial, provided that the conditions laid down in this Regulation are fulfilled. In particular, clinical trials involving authorized radiopharmaceuticals or well-characterized diagnostic imaging agents,**	Sections 6. and 6.a)

		used within established clinical practice or evidence-based protocols, where the additional procedures do not introduce more than minimal additional risk compared to normal clinical practice, may justify risk-proportionate assessment and supervision approaches.	
Article 3 Para 1(a)(ii)	creating new, or significantly expanding, production facilities for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars;	creating new, or significantly expanding, production facilities for biotechnology products, **including decentralized manufacturing capacities where justified by the characteristics of the biotechnology concerned,** in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars;	Section 2.
Article 3 Para 1(d)(iv) new		**supporting the development and retention of interdisciplinary talent and clinician-scientist expertise at the interface of research, clinical practice and biotechnology innovation.**	Section 2. c)
Article 33 Para 6a new		**Data generated and processed under this framework should, where appropriate and in accordance with applicable Union data protection and sectoral legislation, adhere to the principles of findability, accessibility, interoperability and reusability (FAIR principles).**	Section 4.
Article 36 Para 5	The Foresight Panel shall consist of scientific and regulatory experts from the SoHO Coordination Board ('the SCB'), the Medical Devices Coordination Group ('the MDCG'), the Coordination group on Health Technology Assessment ('the HTACG'), the Agency and the competent authorities of the Member States, appointed by the Commission in view of their regulatory, scientific or technical expertise in the relevant identified fields and frameworks. The panel may invite external experts	The Foresight Panel shall consist of scientific and regulatory experts from the SoHO Coordination Board ('the SCB'), the Medical Devices Coordination Group ('the MDCG'), the Coordination group on Health Technology Assessment ('the HTACG'), the Agency and the competent authorities of the Member States, appointed by the Commission in view of their regulatory, scientific or technical expertise in the relevant identified fields and frameworks, **including radiation protection.** The	Section 5. a)

	selected to assist with specific tasks when such relevant external expertise is needed.	panel may invite external experts selected to assist with specific tasks when such relevant external expertise is needed.	
Article 40 Para 6	When assessing the applications received in accordance with paragraph 3 of this Article and when developing and implementing the sandbox plan, the Commission may consult the Agency, the SCB, the MDCG, or the Foresight Panel, as appropriate.	When assessing the applications received in accordance with paragraph 3 of this Article and when developing and implementing the sandbox plan, the Commission may consult the Agency, the SCB, the MDCG, **radiation protection authorities,** or the Foresight Panel, as appropriate.	Section 5. b)
Article 58 Para 13 CTR Article 14a Para 9(aa) new		**support practical and technical coordination between the applicable regulatory frameworks and authorities for combined studies, including where relevant the use of medical devices, software and artificial intelligence-supported tools in clinical trials;**	Section 6. h)
Article 58 Para CTR Article 41 Para 5	Reporting requirements of adverse events and serious adverse events for minimal-intervention and low-intervention clinical trials shall be simplified by applying a risk-based approach. Any such adaptation should be clearly stated and justified in the protocol by the sponsor.	Reporting requirements of adverse events and serious adverse events for minimal-intervention and low-intervention clinical trials shall be simplified by applying a risk-based approach. Any such adaptation should be clearly stated and justified in the protocol by the sponsor. **Reporting requirements for diagnostic minimal-intervention and low-intervention clinical trials shall be limited to unexpected adverse events and serious adverse events.**	Section 6. c)