



2025/0406(COD)

2.10.2026

OPINION

of the Committee on the Environment, Climate and Food Safety

for the Committee on Public Health and the Committee on Industry, Research and Energy

on the proposal for a regulation of the European Parliament and of the Council 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) (COM(2025)1022 – C10-0363/2025 – 2025/0406(COD))

Rapporteur for opinion: Nicolás González Casares

PA_Legam

SHORT JUSTIFICATION

The rapporteur welcomes the Commission's proposal for a European Biotech Act as an important step towards strengthening the Union's competitiveness in health biotechnology and biomanufacturing. The proposal directly amends legislation within the competence of the Committee on the Environment, Climate and Food Safety, including the General Food Law and the mandate of the European Food Safety Authority (EFSA). The amendments in this opinion therefore seek to strike an appropriate balance. On the one hand, they foster innovation in biotechnology. On the other, they maintain the high standards of consumer protection, environmental safety and scientific integrity that underpin Union legislation. Regulatory frameworks should be agile enough to accommodate technological progress, but innovation must develop under conditions that ensure transparency, accountability and public trust.

To that end, the opinion anchors the Regulation in the One Health approach. It recalls that implementation should follow the precautionary principle and be based on science and risk. It also recalls the Union's obligations on fair and equitable benefit-sharing under the Nagoya Protocol.

Scientific integrity and EFSA governance. Pre-submission advice can help applicants, in particular SMEs and first-time applicants, prepare higher-quality dossiers and support innovation. However, appropriate separation between advisory and assessment functions remains essential to avoid conflicts of interest and to maintain confidence in the impartiality of risk assessment. The opinion therefore reinstates the principle that staff providing pre-submission advice should not take part in the risk assessment of the same application. Where specific expertise makes their involvement unavoidable, they may participate only subject to a documented declaration of interests and internal safeguards, and may neither chair the panel nor take part in adopting the opinion. A stronger role for EFSA staff in chairing scientific panels may improve coherence and efficiency. That role must remain functionally independent from pre-submission advice and preserve the independence, diversity and plurality of scientific expertise, since opinions remain the collective responsibility of independent experts. Because these new tasks require adequate means, the opinion calls for the additional resources EFSA needs, equivalent to 28 full-time posts. Any fees should be proportionate and safeguard the Authority's independence, with stable public funding where fees are insufficient. The opinion also strengthens EFSA's role in promoting New Approach Methodologies, with a view to phasing out animal testing without lowering safety standards.

Regulatory sandboxes and novel foods. Products that reach consumers directly should not be excluded from structured regulatory oversight merely because they are innovative. The opinion therefore removes the blanket exclusion of novel foods from regulatory sandboxes, on the basis of a science-based approach. Sandboxes involving novel foods may only generate scientific evidence and support regulatory learning, without replacing or prejudging the authorisation procedure under Regulation (EU) 2015/2283. No such sandbox may be established on the territory of a Member State without its prior express consent. The opinion also enables the Commission, on the recommendation of EFSA, to establish regulatory sandboxes at Union level. These complement national initiatives, promote consistency across the Single Market, facilitate access to specialised scientific expertise and reduce fragmentation. All sandboxes are subject to strengthened safeguards: A justification of why existing pathways are not available or appropriate; informed consumer consent, labelling and

traceability; stakeholder engagement, including civil society; and publicly available reporting.

Genetically modified organisms in medicinal products. The exemption from environmental risk assessment for certain advanced therapy medicinal products containing GMOs is maintained. However, it is limited to products presenting no or negligible risk to human health, animal health, ecosystems and the environment. Applicants must provide a reasoned justification rather than rely solely on a self-declaration. This proportionate safeguard enhances legal certainty, scientific robustness and public confidence without creating unnecessary barriers to innovation. For veterinary medicinal products containing GMOs, the non-application of Union GMO legislation is made conditional on an environmental risk assessment having been carried out. It remains without prejudice to the rules applicable to food and feed derived from treated animals.

Strategic projects and environmental assessments. Health biotechnology strategic projects remain recognised as being of public interest. However, the opinion provides that they *may*, rather than *shall*, benefit from tacit approval in environmental assessment procedures. Projects receiving public funding must fully comply with Union ethical, environmental and social legislation. Designated authorities must have the capacity to assess these criteria, and the public concerned must be informed and consulted within a reasonable timeframe.

Supplementary protection and zoonotic diseases. The rapporteur considers that the scope of the proposed supplementary protection certificate (SPC) should be limited. The extension for veterinary medicinal products targeting zoonotic diseases lacks a proper econometric impact assessment. There is insufficient economic evidence that additional exclusivity would effectively address the underlying market failures in this sector.

Demand for zoonotic vaccines is often episodic, outbreak-driven and highly dependent on public health circumstances, which limits the incentive value of a fixed exclusivity extension. Veterinary vaccines also require rapid adaptation to emerging pathogens and circulating variants. Innovation in this field therefore depends on regulatory flexibility and scientific responsiveness rather than prolonged protection of a specific product. Extending intellectual property protection is thus poorly suited to stimulating investment in this field, and it is not an appropriate instrument for zoonosis and pandemic prevention and preparedness.

Where an extension of supplementary protection is nonetheless retained, it must not result in a transfer of value from public health systems and citizens to industry without a clear counterpart. Any such extension should be strictly conditional on two things: genuine and verifiable investment in research and development and manufacturing capacity in the Union, according to Commission proposal as a minimum.

This orientation is consistent with the approach emerging in the Committee on Legal Affairs. It reflects a clear preference on the part of Parliament: incentives must deliver tangible public benefits, in particular in terms of access, rather than additional exclusivity alone.

Other possible mechanism include push incentives, such as research grants, public-private partnerships and support for clinical development. They also include pull incentives, such as advance purchase commitments, market guarantees and strategic procurement mechanisms. A balanced push-pull approach would provide stronger and more predictable incentives for innovation, while aligning public investment with public health preparedness, animal health objectives and societal needs. Thus, more targeted policy instruments are better adapted to the

specific characteristics of zoonotic vaccine development specifically in animal health.

In this spirit, the opinion introduces a One Health Priority Product designation for veterinary medicinal products addressing zoonotic diseases of significant public health relevance. Designated products will be eligible for priority scientific advice and enhanced regulatory support, accelerated authorisation procedures, reduced fees, priority consideration within instruments managed by the Health Emergency Preparedness and Response Authority (HERA).

The designation confers no exclusive rights beyond those expressly provided for and does not affect requirements on quality, safety and efficacy.

Taken together, these amendments reinforce an innovation-friendly regulatory framework that remains firmly grounded in scientific evidence, precaution, transparency and democratic accountability. The opinion places human and animal health, and the prevention of and preparedness for zoonoses and pandemics, at the centre of the Regulation. It favours targeted support, regulatory efficiency and a strong, independent EFSA over the extension of market exclusivity. It thereby seeks to ensure that technological advances deliver benefits to society, including access for citizens, while safeguarding human health, animal health, consumers, biodiversity and the environment.

AMENDMENT

The Committee on the Environment, Climate and Food Safety submits the following to the Committee on Public Health and the Committee on Industry, Research and Energy, as the committees responsible:

Amendment 1

Proposal for a regulation

Recital 1

Text proposed by the Commission

(1) Biotechnology is a strategic technology central for the Union's competitiveness, strategic autonomy and innovation leadership. It has applications across several sectors, with prominence in the health area. In 2021, the Union was the second largest contributor to the global value of biotechnologies. Between 2008 and 2018, the biotechnology industry in the Union grew more than twice as fast as the overall economy, making it one of the fastest growing innovative industries in the Union. Health biotechnology specifically contributes over 80% to the value of the overall biotechnology market and it is a key driver of today's innovative medical industry. Biological medicines, including biosimilars count for 40% of overall pharmaceutical sales in the Union.

Amendment

(1) Biotechnology is a strategic technology central for the Union's competitiveness, strategic autonomy and innovation leadership. It has applications across several sectors, with prominence in the health area. ***While offering major opportunities for innovation, biotechnology and biomanufacturing should also be developed in a manner that preserves and protects the quality of the environment, as well as human health, in accordance with principles enshrined in Article 191 TFEU.*** In 2021, the Union was the second largest contributor to the global value of biotechnologies. Between 2008 and 2018, the biotechnology industry in the Union grew more than twice as fast as the overall economy, making it one of the fastest growing innovative industries in the Union. Health biotechnology specifically contributes over 80% to the value of the overall biotechnology market and it is a key driver of today's innovative medical industry. Biological medicines, including biosimilars count for 40% of overall pharmaceutical sales in the Union.

Amendment 2

Proposal for a regulation

Recital 1 a (new)

(1a) This Regulation should uphold the level of protection established under Union legislation on environmental protection, genetically modified organisms, chemical safety, waste management, occupational safety, animal welfare, veterinary public health, food and feed safety, substances of human origin, medicinal products, clinical trials, data protection and biosecurity. Compliance with such Union legislation should remain a precondition for authorisation, funding, accelerated procedures or access to regulatory support under this Regulation.

Amendment 3

Proposal for a regulation Recital 4

(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity.

(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety, ***food and feed security*** and biosecurity, ***and ensuring that resulting biotechnology medicinal products are accessible, affordable and can effectively answer to patients' needs***

across the Union.

Amendment 4

Proposal for a regulation

Recital 5

Text proposed by the Commission

(5) Given the importance of health biotechnology amongst the other applications of biotechnology as referred to in recital (1), it is appropriate that this Regulation focusses on, and sets out specific measures for, the health dimension of biotechnology. To ensure the effectiveness of this Regulation, its scope of application should extend to health biotechnology in a comprehensive manner and cover health within the wide meaning of Article 168 TFEU on the protection of public health.

Amendment

(5) Given the importance of health biotechnology amongst the other applications of biotechnology as referred to in recital (1), it is appropriate that this Regulation focusses on, and sets out specific measures for, the health dimension of biotechnology. To ensure the effectiveness of this Regulation, its scope of application should extend to health biotechnology in a comprehensive manner and cover health within the wide meaning of Article 168 TFEU on the protection of public health, ***as well as of Article 191 TFEU aiming at a high level of protection of the environment and human health in line with the ‘One Health’ approach and the precautionary principle. The regulatory framework should be science-based, and proportionate to the actual risk profile of the product or activity concerned, while ensuring a high level of protection of human health, animal health and the environment.***

Amendment 5

Proposal for a regulation

Recital 6

Text proposed by the Commission

(6) Article 168(1) TFEU emphasises that a high level of human health protection is to be ensured when defining and implementing all Union policies and activities. Article 168(4) TFEU clarifies that this objective is, amongst others, to be pursued through measures setting high

Amendment

(6) Article 168(1) TFEU emphasises that a high level of human health protection is to be ensured when defining and implementing all Union policies and activities. Article 168(4) TFEU clarifies that this objective is, amongst others, to be pursued through measures setting high

standards of quality and safety for medicinal products and devices for medical use and of organs and substances of human origin, blood and blood derivatives, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health.

standards of quality and safety for medicinal products and devices for medical use and of organs and substances of human origin, blood and blood derivatives, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health. ***In this context, respect for the precautionary principle enshrined in Article 191(2) TFEU is key.***

Amendment 6

Proposal for a regulation Recital 7

Text proposed by the Commission

(7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems¹, this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities.

¹ European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024,

Amendment

(7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems¹, this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities. ***Particular attention should also be given to ensuring equitable access to such health technologies and to enable their development across the Union with a view to reducing disparities between Member States and among patients in general.***

¹ European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024,

Amendment 7

Proposal for a regulation Recital 10

Text proposed by the Commission

(10) This Regulation should not affect to the application of the Directive 2010/63/EU of the European Parliament and of the Council⁴ on the protection of animals used for scientific purposes and of Regulation (EC) 2006/1907 of the European Parliament and of the Council⁵.

⁴ Consolidated text: Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance). ELI: <http://data.europa.eu/eli/dir/2010/63/2019-06-26>

⁵ Consolidated text: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive

Amendment

(10) This Regulation should not affect to the application of the Directive 2010/63/EU of the European Parliament and of the Council⁴ on the protection of animals used for scientific purposes and of Regulation (EC) 2006/1907 of the European Parliament and of the Council⁵. ***Directive 2010/63/EU sets the goal of full replacement of procedures on live animals for scientific and educational purposes as soon as scientifically possible, while applying the principle of replacement, reduction and refinement. In line with that objective, and taking into account the Commission Roadmap towards phasing out animal testing, this Regulation should support the development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies (NAMs), where scientifically appropriate, and feasible.***

⁴ Consolidated text: Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance). ELI: <http://data.europa.eu/eli/dir/2010/63/2019-06-26>

⁵ Consolidated text: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive

1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). ELI: <http://data.europa.eu/eli/reg/2006/1907/2025-09-01>.

1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). ELI: <http://data.europa.eu/eli/reg/2006/1907/2025-09-01>.

Amendment 8

Proposal for a regulation

Recital 13

Text proposed by the Commission

(13) NAMs applied in biological research, early discovery, preclinical development, and the regulatory and quality testing of medicinal products and medical technologies, have the potential to generate scientific and technological data that are comparable to, or in some cases more informative and generated more rapidly than, those obtained through current standard methods. The resulting advantage will contribute to strengthen the innovation ecosystem and enhanced European competitiveness in biotechnology.

Amendment

(13) NAMs applied in biological research, early discovery, preclinical development, and the regulatory and quality testing of medicinal products and medical technologies, ***such as advanced in vitro systems, microphysiological systems, and in silico approaches***, have the potential to generate scientific and technological data that are comparable to, or in some cases more informative and generated more rapidly than, those obtained through current standard methods. The resulting advantage will contribute to strengthen the innovation ecosystem and enhanced European competitiveness in biotechnology.

Amendment 9

Proposal for a regulation

Recital 17

Text proposed by the Commission

(17) Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects

Amendment

(17) Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects

aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners. Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation.

aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners. ***This should include the development of skills and training programmes related to NAMs, as well as their application in regulatory science and safety assessment.*** Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation.

Amendment 10

Proposal for a regulation Recital 20

Text proposed by the Commission

(20) To provide an evidence base for future Union action to further strengthen the biotechnology and biomanufacturing sectors, the Commission should carry out a strategic mapping of the Union's biotechnology ecosystem. That mapping should analyse industrial capacities, infrastructures and facilities relevant to biotechnology research, development, testing and manufacturing, and assess factors affecting the Union's ability to attract and retain investment in biomanufacturing, including access to public and private risk-tolerant capital across all stages of the innovation cycle, the development and coordination of biotechnology clusters and biomanufacturing ecosystems across the Union, and assess challenges and needs in terms of the workforce.

Amendment 11

Proposal for a regulation
Recital 22

Text proposed by the Commission

(22) In order to ensure a transparent, coherent and efficient process for the identification of health biotechnology strategic projects, each Member State should designate a competent authority responsible for assessing and verifying whether a project fulfils the conditions set out in this Regulation for its recognition as a health biotechnology strategic project. The designated authority should carry out the assessment through a fair, transparent and time-bound process. Where a project is found to fulfil the conditions for recognition as a biotechnology strategic project, the designated authority should issue a formal recognition decision.

Amendment

(22) In order to ensure a transparent, coherent and efficient process for the identification of health biotechnology strategic projects, each Member State should designate a competent authority responsible for assessing and verifying, ***in cooperation with relevant partners,*** whether a project fulfils the conditions set out in this Regulation for its recognition as a health biotechnology strategic project. The designated authority should carry out the assessment through a fair, transparent and time-bound process. Where a project is found to fulfil the conditions for recognition as a biotechnology strategic project, the designated authority should issue a formal recognition decision.

Amendment 12

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission

Amendment

(26a) Biotechnology clusters bring together companies, research institutions and organisations across a range of disciplines whose combined expertise drives innovation in health biotechnology. Given the interconnected nature of the 'One Health' approach underpinning this Regulation, such clusters should not be understood as limited to institutions engaged in human medical research. Veterinary research institutions contribute directly to the development of biotechnology-based veterinary medicinal products and to the prevention, monitoring and treatment of zoonotic diseases, while botanical research institutions contribute plant-based and plant-derived expertise relevant to

biotechnology applications, including in the fields of biomanufacturing feedstocks, natural product discovery and genetic resources. Recognising medical, veterinary and botanical research institutions within the definition of 'biotechnology cluster' ensures that the full breadth of disciplines relevant to health biotechnology innovation can benefit from, and contribute to, the support measures established under this Regulation.

Amendment 13

Proposal for a regulation Recital 32

Text proposed by the Commission

(32) Member States whose territories are concerned by health biotechnology strategic projects or high impact health biotechnology strategic projects should take all appropriate measures to facilitate their timely and effective development and deployment. Such measures should include the provision of administrative support, upon the request of project promoters, as well as, without prejudice to Union competition *law*, of public financial and technical support, with a particular attention paid to SMEs, start-ups and scale-ups.

Amendment

(32) Member States whose territories are concerned by health biotechnology strategic projects or high impact health biotechnology strategic projects should take all appropriate measures to facilitate their timely and effective development and deployment. Such measures should include the provision of administrative support, upon the request of project promoters, as well as, without prejudice to Union ***environment, social and competition legislation***, of public financial and technical support, with a particular attention paid to SMEs, start-ups and scale-ups.

Amendment 14

Proposal for a regulation Recital 47 a (new)

Text proposed by the Commission

Amendment

(47a) The Union's health biotechnology sector is a strategic asset for the Union's competitiveness, resilience and sustainability, and should be anchored in

the 'One Health' approach. Favourable conditions should be created and reinforced for health biotechnology, across the full innovation cycle, from research and development to the timely placing on the Union market and production of biotechnology innovations and products. This should ensure timely, equitable and affordable access to those innovations and products for patients and citizens, while safeguarding and strengthening high standards of protection of human health, patient safety, animal health and welfare, the environment, ethics, the quality of products, food and feed safety and security, and biosecurity. In line with the 'One Health' approach, this Regulation should also contribute to addressing risks linked to zoonotic diseases, antimicrobial resistance, biological threats, food and feed safety, animal health, animal welfare and ecosystem health, through integrated research, surveillance, preparedness and innovation capacities across sectors.

Amendment 15

Proposal for a regulation Recital 47 b (new)

Text proposed by the Commission

Amendment

(47b) This Regulation should be implemented in accordance with the precautionary principle and on the basis of science-based and risk-based principles, with a view to avoiding unnecessary administrative burden and duplication of assessments for economic operators and competent authorities alike.

Amendment 16

Proposal for a regulation Recital 47 c (new)

(47c) Health biotechnology innovation frequently relies on the utilisation of genetic resources and associated traditional knowledge originating within and outside the Union. The Union and all its Member States are Parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, implemented in Union law through Regulation (EU) No 511/2014 of the European Parliament and of the Council. Activities supported or facilitated under this Regulation, including regulatory sandboxes, strategic projects and public funding instruments, should therefore promote the fair and equitable sharing of the benefits arising from the utilisation of genetic resources, in full compliance with applicable access and benefit-sharing obligations, without prejudice to the obligations of users under Regulation (EU) No 511/2014.

Amendment 17

**Proposal for a regulation
Recital 108 a (new)**

(108a) Consistent with the Commission Roadmap towards phasing out animal testing for chemical safety assessments, the Authority should build on existing models within the Union agencies, such as pre-submission scientific advice and voluntary data-sharing mechanisms, and the setting up of a dedicated panel to support the development, validation and regulatory acceptance of NAMs in the food and feed sector.

Amendment 18

Proposal for a regulation Recital 109

Text proposed by the Commission

(109) Considering the increasing prevalence of diet-related health issues, it is essential to expand the Authority's mandate to encompass all aspects of nutrition and to enable it to provide advice concerning the nutritional properties of food products and practices, including those derived from advanced biotechnological processes.

Amendment

(109) Considering the increasing prevalence of diet-related health issues, it is essential to expand the Authority's mandate to encompass all aspects of nutrition and to enable it to provide advice concerning the nutritional properties of food products and practices, including those derived from advanced biotechnological processes. ***In exercising this mandate, the Authority should pay particular attention to foods high in fat, sugar or salt (HFSS), as well as ultra-processed foods (UPFs), given their documented impact on public health, and should ensure that its scientific advice takes due account of the Union's public-health objectives.***

Amendment 19

Proposal for a regulation Recital 110

Text proposed by the Commission

(110) It has been observed that a significant number of application and notification dossiers submitted to the Authority are either incomplete or do not meet the applicable regulatory and scientific specifications requirements to enable the best quality scientific assessment by the Authority, resulting in the need for requests for additional information during the risk assessment process and, consequently, leading to sometimes significant delays. This is also the case where biotechnology innovations and products are concerned, as such products would benefit strongly from pre-submission scientific advice on study

Amendment

(110) It has been observed that a significant number of application and notification dossiers submitted to the Authority are either incomplete or do not meet the applicable regulatory and scientific specifications requirements to enable the best quality scientific assessment by the Authority, resulting in the need for requests for additional information during the risk assessment process and, consequently, leading to sometimes significant delays. This is also the case where biotechnology innovations and products are concerned, as such products would benefit strongly from pre-submission scientific advice on study

design and testing strategies. Applicants or notifiers of such products, in particular small and medium-sized enterprises do not always have a clear understanding of the applicable regulatory and scientific requirements when compiling application dossiers, in particular as regards the types and details of studies to conduct. It is thus appropriate to enlarge the scope of the general pre-submission advice provided by the Authority at the request of a potential applicant or notifier to encompass non-committal advice on regulatory aspects including applicable rules and guidance documents, as well as scientific advice on study design and testing strategies. This advice should be provided by the staff and experts of the Authority to ensure the most updated scientific advice. Given the broadening of the scope of the general pre-submission advice which is already available for both new and renewals of approvals/authorisations, it is no longer necessary to provide for a specific pre-submission advice for renewals.

design and testing strategies. Applicants or notifiers of such products, in particular small and medium-sized enterprises do not always have a clear understanding of the applicable regulatory and scientific requirements when compiling application dossiers, in particular as regards the types and details of studies to conduct. It is thus appropriate to enlarge the scope of the general pre-submission advice provided by the Authority at the request of a potential applicant or notifier to encompass non-committal advice on regulatory aspects including applicable rules and guidance documents, as well as scientific advice on study design and testing strategies. This advice should be provided by the staff and experts of the Authority to ensure the most updated scientific advice. ***This advice should be provided in a manner that preserves a clear separation between advisory activities and scientific risk assessment, to safeguard the Authority's independence.*** Given the broadening of the scope of the general pre-submission advice which is already available for both new and renewals of approvals/authorisations, it is no longer necessary to provide for a specific pre-submission advice for renewals.

Amendment 20

Proposal for a regulation Recital 113

Text proposed by the Commission

(113) The food and feed sector is experiencing rapid technological advancements, including biotechnology, AI, smart farming techniques, development of new approach methodologies, that could contribute to reduction of animal testing and circular economy practices promoting resource efficiency and waste reduction. It is therefore appropriate to provide Member States with the possibility of setting up

Amendment

(113) The food and feed sector is experiencing rapid technological advancements, including biotechnology, AI, smart farming techniques, development of new approach methodologies, that could contribute to reduction ***and replacement*** of animal testing and circular economy practices, ***sustainable and resilient food systems***, promoting resource efficiency and waste reduction. It is therefore appropriate

regulatory sandboxes that can provide *an* environment for the testing of those innovations in a controlled manner, incentivising research and development, whilst allowing for adaptive regulatory practices that can be modified based on feedback and results from live trials. Regulation (EC) No 178/2002 should therefore be amended accordingly.

to provide Member States with the possibility of setting up regulatory sandboxes, *where pathways for controlled testing, notification or authorisation are not available or appropriate*, that can provide *a flexible and efficient* environment for the testing of those innovations in a controlled manner, *under clear, transparent, proportionate and predictable conditions, including appropriate protection of commercially confidential information*, incentivising research and development, whilst allowing for adaptive regulatory practices that can be modified based on feedback and results from live trials. Regulation (EC) No 178/2002 should therefore be amended accordingly.

Amendment 21

Proposal for a regulation Recital 114

Text proposed by the Commission

(114) Given the diversity of sectors covered by Union food law, and the fact that Member States have diverse food systems, cultural preferences, local market conditions, and research and risk assessment bodies, regulatory sandboxes should be established a national level in order to ensure the necessary flexibility to allow for experimentation specifically tailored to address local needs, preferences, and consumer behaviours. For the same reasons, and in order to support innovation along the whole food chain, regulatory sandboxes should be allowed also at retail level and, thus, making available products under the regulatory sandboxes to food business operators or consumers should not be considered as placing on the market. However, in order to ensure that the establishment of regulatory sandboxes does not jeopardise food safety or consumers' information and that they are established

Amendment

(114) Given the diversity of sectors covered by Union food law, and the fact that Member States have diverse food systems, cultural preferences, local market conditions, *research and innovation ecosystems*, and research and risk assessment bodies, regulatory sandboxes should be established a national level in order to ensure the necessary flexibility to allow for experimentation specifically tailored to address local needs, preferences, and consumer behaviours. For the same reasons, and in order to support innovation along the whole food chain, regulatory sandboxes should be allowed also at retail level and, thus, making available products under the regulatory sandboxes to food business operators or consumers should not be considered as placing on the market. However, in order to ensure that the establishment of regulatory sandboxes does not jeopardise food safety or consumers'

and function in such a way as to enable the collection of sound and useful information to inform future regulatory changes, rules should be laid down concerning the objectives pursued within regulatory sandboxes, the modalities for their adoption, amendment and revocation, the control of the activities carried out under the regulatory sandbox, monitoring and reporting as well as rules ensuring the protection of human and animal health and of the environment.

information and that they are established and function in such a way as to enable the collection of sound and useful information to inform future regulatory changes, rules should be laid down concerning the objectives pursued within regulatory sandboxes, the modalities for their adoption, amendment and revocation, the control of the activities carried out under the regulatory sandbox, monitoring and reporting, ***facilitate the exchange of experience and best practices between Member States and promote efficient involvement of the Authority where scientific input is needed***, as well as rules ensuring the protection of human and animal health and of the environment.

Amendment 22

Proposal for a regulation Recital 114 a (new)

Text proposed by the Commission

Amendment

(114a) In order to make regulatory sandboxes operationally useful for innovators and competent authorities, the Authority should, where appropriate and upon request, be able to contribute scientific guidance to sandbox design, including as regards study design, data generation, data quality and proportionate risk-mitigation measures. Such support should remain without prejudice to the independence of any subsequent risk assessment.

Amendment 23

Proposal for a regulation Recital 115

Text proposed by the Commission

Amendment

(115) Regulatory sandboxes should ***not be allowed for some products. Experience***

(115) Regulatory sandboxes ***can provide a structured context for testing under a***

has shown that certain types of novel foods trigger ethical or cultural concerns among various consumer segments regarding their acceptability. ***Since*** those aspects ***are best*** addressed within the applicable rigorous regulatory framework established by Regulation (EU) 2015/2283 of the European Parliament and of the Council⁴⁸, ***it is appropriate to exclude novel foods from the scope of*** regulatory sandboxes. For GMOs legal pathways exist to allow testing of innovations, such as under Part B of Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMOs) for purposes other than placing on the market, and there should not be a duplication of paths in order to maintain legal certainty. For this reason, regulatory sandboxes should be restricted to products containing or consisting of GMOs subject to authorisation under Part C of Directive 2001/18/EC. As regards innovations concerning novel plastic recycling technologies for plastics intended to come into contact with food, chapter IV of Commission Regulation (EU) 2022/1616⁴⁹ already establishes a framework that is meant to encourage the development of such novel technologies without prior authorisation. To ensure uniform rules on the development of novel recycling technologies that safeguard the health of the consumers, it is appropriate to exclude the development of recycling technologies from the possible use of regulatory sandboxes and rely instead on the procedure established in chapter IV of Regulation (EU) 2022/1616.

controlled framework and support responsible innovation, early regulatory learning, evidence generation and proportionate testing under strict supervision, and should only be used where pathways for controlled testing, notification or authorisation do not yet exist, while ensuring a high level of protection of human health, animal health, animal welfare, food and feed safety, consumer protection and the environment. ***However,*** certain types of novel foods ***may*** trigger ethical or cultural concerns among various consumer segments regarding their acceptability. Those aspects ***should continue to be*** addressed within the applicable rigorous regulatory framework established by Regulation (EU) 2015/2283 of the European Parliament and of the Council. ***However, this should not prevent Member States from using*** regulatory sandboxes ***to generate evidence, test data requirements, study designs, production processes and safety assessment approaches for innovative novel foods.*** ***Where a proposed regulatory sandbox concerns novel foods or innovative food production methods, ethical, cultural or consumer concerns should be duly substantiated, assessed on a case-by-case basis and taken into account where relevant under applicable Union or national law; such assessment should not prejudice the primacy of science-based risk assessment.*** ***In particular, as regards regulatory sandboxes concerning novel foods, participation by Member States in national and Union-level regulatory sandboxes should be voluntary. No regulatory sandbox concerning novel foods should be established, implemented or operated within the territory of a Member State pursuant to this Regulation or to acts adopted pursuant to it without the prior express consent of the Member State concerned.*** For GMOs legal pathways exist to allow testing of innovations, such as under Part B of

Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMOs) for purposes other than placing on the market, and there should not be a duplication of paths in order to maintain legal certainty. For this reason, regulatory sandboxes should be restricted to products containing or consisting of GMOs subject to authorisation under Part C of Directive 2001/18/EC. As regards innovations concerning novel plastic recycling technologies for plastics intended to come into contact with food, chapter IV of Commission Regulation (EU) 2022/1616 already establishes a framework that is meant to encourage the development of such novel technologies without prior authorisation. To ensure uniform rules on the development of novel recycling technologies that safeguard the health of the consumers, it is appropriate to exclude the development of recycling technologies from the possible use of regulatory sandboxes and rely instead on the procedure established in chapter IV of Regulation (EU) 2022/1616.

⁴⁸ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1, ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>).

⁴⁹ Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008 (OJ L 243, 20.9.2022, p. 3, ELI: <http://data.europa.eu/eli/reg/2022/1616/oj>).

⁴⁸ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1, ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>).

⁴⁹ Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008 (OJ L 243, 20.9.2022, p. 3, ELI: <http://data.europa.eu/eli/reg/2022/1616/oj>).

Amendment 24

Proposal for a regulation Recital 115 a (new)

Text proposed by the Commission

Amendment

(115a) Innovative food technologies, including novel foods, precision fermentation, contained-use microbial production systems and other biotechnology-enabled production methods, have the potential to contribute to more sustainable, resilient and diversified food systems in the Union. They could support food safety, food and nutrition security, resource efficiency, improved nutritional outcomes and, where substantiated by evidence, reductions in environmental pressures, including greenhouse gas emissions, land use and water use, while contributing to the prevention of zoonotic diseases and antimicrobial resistance in line with a ‘One Health’ approach. Data requirements and regulatory pathways for such innovations should be predictable, proportionate and science-based. The development and uptake of such innovations should be based on independent scientific assessment, transparency, consumer protection and full compliance with Union food and feed safety law.

Amendment 25

Proposal for a regulation Recital 117

Text proposed by the Commission

Amendment

(117) Considering the additional financial burden established on the Authority with the expansion of its mandate following the amendments set out in this Regulation, the possibility of establishing fees in order to fully or partially fund EFSA’s new tasks

(117) Considering the additional financial burden established on the Authority with the expansion of its mandate following the amendments set out in this Regulation, the possibility of establishing fees in order to fully or partially fund EFSA’s new tasks

could be considered.

should be assessed in order to ensure the effective, timely and sustainable performance of the Authority's tasks. Any such fees should be proportionate, cost-related and designed so as not to unduly burden small and medium-sized enterprises, start-ups or research-driven undertakings, while fully safeguarding the Authority's independence and scientific integrity. Where fees are not sufficient or appropriate, additional resources should be ensured through stable and sustainable public funding under the Union budget.

Amendment 26

Proposal for a regulation Recital 117 a (new)

Text proposed by the Commission

Amendment

(117a) EFSA's scientific opinions are adopted collectively by its Scientific Committee and Scientific Panels, which comprise independent experts and reach conclusions through a robust, transparent and collegial decision-making process, distinct from the role of the Authority's expert staff, who operate under the Authority's policy of independence.

Amendment 27

Proposal for a regulation Recital 119

Text proposed by the Commission

Amendment

(119) Consequently, when controlling under Regulation (EU) No 536/2014 for risks from the deliberate release into the environment of GMOs, a risk-proportionate approach should be applied and Regulation (EC) No 1394/2007 should be amended with respect to certain, clearly delineated categories of advanced

(119) Consequently, when controlling under Regulation (EU) No 536/2014 for risks from the deliberate release into the environment of GMOs, a risk-proportionate approach should be applied, *in order to avoid unnecessary duplication, administrative burden, divergent national requirements and delays to clinical trials,*

investigational therapy medicinal products that consist or contain GMOs, which present no or negligible risks to human health and the environment. Whilst it is appropriate to exempt such clearly delineated categories of advanced investigational therapy medicinal products from the requirement to submit an environmental risk assessment, sponsors of clinical trials should, however, submit a declaration as part of the clinical trial application that explains why the advanced investigational therapy medicinal products concerned falls into one or more of the specific categories of products presenting no or negligible risks to human health and the environment. The Committee for Medicinal Products for Human Use (CHMP) referred to in Article [148] of Regulation [...] [revised Regulation No (EC) 726/2004] should verify this declaration. For the same considerations of a risk-proportionate approach, the above-mentioned categories of advanced investigational therapy medicinal products should also be exempted from the requirements of Regulation (EU) No 536/2014 regarding manufacturing and import. Annex I to the Regulation (EU) No 536/2014 should also be amended to ensure consistency with the aforementioned amendments to the Regulation (EC) No 1394/2007.

and Regulation (EC) No 1394/2007 should be amended with respect to certain, clearly delineated categories of advanced investigational therapy medicinal products that consist or contain GMOs, which present no or negligible risks to human health and the environment. Whilst it is appropriate to exempt such clearly delineated categories of advanced investigational therapy medicinal products from the requirement to submit an environmental risk assessment, sponsors of clinical trials should, however, submit a declaration as part of the clinical trial application that explains why the advanced investigational therapy medicinal products concerned falls into one or more of the specific categories of products presenting no or negligible risks to human health and the environment. The Committee for Medicinal Products for Human Use (CHMP) referred to in Article [148] of Regulation [...] [revised Regulation No (EC) 726/2004] should verify this declaration. For the same considerations of a risk-proportionate approach, the above-mentioned categories of advanced investigational therapy medicinal products should also be exempted from the requirements of Regulation (EU) No 536/2014 regarding manufacturing and import. Annex I to the Regulation (EU) No 536/2014 should also be amended to ensure consistency with the aforementioned amendments to the Regulation (EC) No 1394/2007.

Amendment 28

Proposal for a regulation Recital 120 a (new)

Text proposed by the Commission

Amendment

(120a) Advanced therapy medicinal products containing genetically modified organisms may, depending on their biological characteristics, result in

environmental exposure through shedding, persistence or dissemination. Exemptions from environmental risk assessment requirements should therefore be limited to situations where robust scientific evidence demonstrates that risks to human health, animal health and the environment are absent or negligible. In accordance with Article 191(2) TFEU, the precautionary principle should guide the application of such exemptions.

Amendment 29

Proposal for a regulation

Article 1 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(aa) the promotion of scientific freedom, open and collaborative science, and the development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies (NAMs), where scientifically appropriate, in order to support human-relevant evidence generation and contribute to the replacement, reduction and refinement of animal testing and use in research, development, manufacturing, clinical trials and regulatory safety assessment;

Amendment 30

Proposal for a regulation

Article 1 – paragraph 2 – point d

Text proposed by the Commission

Amendment

(d) the support for funding of, investments in, and access to capital for biotechnology companies and projects;

(d) the support for funding of, investments in, and access to capital for biotechnology companies and projects, *as well as social, animal welfare and environmental conditions;*

Amendment 31

Proposal for a regulation

Article 1 – paragraph 2 – point f

Text proposed by the Commission

(f) the application in a facilitated manner of advanced technologies, including AI in biological applications, into the Union's health biotechnology ecosystems, while monitoring and mitigating, in line with the Union harmonisation legislation on AI, biological risks arising from the use of such technologies;

Amendment

(f) the application in a facilitated manner of advanced technologies, including ***ethical use of*** AI in biological applications, into the Union's health biotechnology ecosystems, while monitoring ***and preventing*** and mitigating, in line with the Union harmonisation legislation on AI, biological risks arising from the use of such technologies;

Amendment 32

Proposal for a regulation

Article 1 – paragraph 2 – point g

Text proposed by the Commission

(g) the placing on the market in particular of health biotechnology products and biotechnology services in accelerated and streamlined procedures;

Amendment

(g) the placing on the market in particular of health biotechnology products and biotechnology services in accelerated and streamlined procedures, ***while respecting existing Union environmental, safety and social regulations and standards.***

Amendment 33

Proposal for a regulation

Article 1 – paragraph 2 – point h a (new)

Text proposed by the Commission

Amendment

(ha) the promotion of fair and equitable sharing of benefits arising from genetic resources in line with the Nagoya protocol.

Amendment 34

Proposal for a regulation
Article 1 – paragraph 3

Text proposed by the Commission

3. This Regulation applies to health biotechnology innovations and products and their ecosystem during their entire lifecycle, including related research, funding, development, innovation, testing, validation, manufacturing, placing on the market, and use activities.

Amendment

3. This Regulation applies to health biotechnology innovations and products and their ecosystem during their entire lifecycle, including related research, funding, development, innovation, testing, validation, manufacturing, placing on the market, and use activities, ***as well as aspects related to the equitable access to, and the affordability of, those innovations and products.***

Amendment 35

Proposal for a regulation
Article 1 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. The implementation of this Regulation shall ensure coherence with future Union initiatives addressing emerging biotechnologies and industrial biotechnology, in particular where measures under this Regulation concern biomanufacturing, data, AI, regulatory simplification, funding and infrastructures.

Amendment 36

Proposal for a regulation
Article 1 – paragraph 5

Text proposed by the Commission

5. This Regulation does not affect the application of Directive 2010/63/EU on the protection of animals used for scientific purposes and of Regulation (EU) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction

Amendment

5. This Regulation does not affect the application of Directive 2010/63/EU on the protection of animals used for scientific purposes and of Regulation (EU) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), ***while supporting***

of Chemicals (REACH).

the development, validation, regulatory acceptance and uptake of NAMs in biotechnology research, development, risk assessment and clinical trial processes.

Amendment 37

Proposal for a regulation

Article 2 – paragraph 1 – point 6

Text proposed by the Commission

(6) ‘biotechnology cluster’ means a geographic concentration of interconnected companies, research institutions and organisations focused on biotechnology and life sciences, fostering collaboration and innovation;

Amendment

(6) ‘biotechnology cluster’ means a geographic concentration of interconnected companies, research institutions and organisations focused on biotechnology and life sciences ***including medical, veterinary and botanical and other relevant institutions***, fostering collaboration and innovation;

Amendment 38

Proposal for a regulation

Article 2 – paragraph 1 – point 19 a (new)

Text proposed by the Commission

Amendment

(19a) ‘One Health’ means One Health as defined in Article 3, point (7), of Regulation (EU) 2022/2371 of the European Parliament and of the Council.

Amendment 39

Proposal for a regulation

Article 3 – paragraph 1 – introductory part

Text proposed by the Commission

1. ***To enable*** access to the support measures ***laid down in Section 2 of Chapter II***, Member States shall recognise ***projects located in the Union***, by means of a reasoned decision, ***as*** health biotechnology ***strategic projects*** if they

Amendment

1. ***In order to allow*** access to the support measures ***provided for in Chapter II, Section 2***, Member States shall recognise, by means of a reasoned decision, ***projects located in the Union as strategic projects in the field of health***

make a substantial contribution to at least one of the following specific objectives:

biotechnology if they ***contribute substantially to the achievement of*** at least one of the following specific objectives:

Amendment 40

Proposal for a regulation

Article 3 – paragraph 1 – point a – point iii

Text proposed by the Commission

(iii) creating or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies;

Amendment

(iii) creating or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies, ***including process innovation, modernisation, digitalisation, scaling or enabling of production and manufacturing processes;***

Amendment 41

Proposal for a regulation

Article 3 – paragraph 1 – point a – point iv a (new)

Text proposed by the Commission

Amendment

(iva) developing, expanding or upgrading nuclear medicine, radiopharmaceutical, imaging or theranostic infrastructures, where they support the development, testing, validation, manufacturing, quality control or clinical translation of health biotechnology products or medical technologies;

Amendment 42

Proposal for a regulation

Article 3 – paragraph 1 – point a – point v

Text proposed by the Commission

(v) ***integrating*** advanced digital and ***AI-driven*** manufacturing and supply-chain

Amendment

(v) ***the reliable integration of*** advanced digital and ***AI-based***

management systems *to enhance* productivity, traceability and sustainability *across* biotechnology value chains;

manufacturing and supply-chain management systems *in order to improve* productivity, traceability and sustainability *throughout* biotechnology value chains;

Amendment 43

Proposal for a regulation

Article 3 – paragraph 1 – point b – point iv

Text proposed by the Commission

(iv) promoting and integrating the use of NAMs in areas such as biological research, discovery and preclinical development, regulatory and quality testing and production of medicinal products and medical technologies.

Amendment

(iv) promoting and integrating the use of NAMs in areas such as biological research, discovery and preclinical development, regulatory and quality testing and production of medicinal products and medical technologies, *chemical and pharmaceutical safety and efficacy assessment, and toxicity testing, irrespective of the regulatory classification or chemical or biological nature of the final product. NAMs enable the prediction of toxicological effects, as well as the modelling of human and species-specific physiology and disease mechanisms, thereby increasing research translatability while progressively replacing animal testing.*

Amendment 44

Proposal for a regulation

Article 3 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) establishing, expanding or upgrading pilot, testing and demonstration infrastructures which, while contributing to the objectives of this Regulation, may also support cross-sectoral learning, regulatory preparedness and scale-up capabilities relevant to emerging biotechnology and biomanufacturing applications.

Amendment 45

Proposal for a regulation

Article 3 – paragraph 1 – point e

Text proposed by the Commission

(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures.

Amendment

(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures, ***like human and veterinary vaccines against transboundary animal diseases and other animal diseases, including zoonotic diseases, where vaccination contributes to the prevention and control of disease and to the reduction of antimicrobial use in animal production.***

Amendment 46

Proposal for a regulation

Article 4 – paragraph 2

Text proposed by the Commission

2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Amendment

2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. ***Environmental and socio-economic impact, including high-quality job creation located in the Union, shall be duly taken into account when defining strong systemic and catalytic potential within the meaning of this Article.*** These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Amendment 47

Proposal for a regulation

Article 5 – paragraph 1 – point c

Text proposed by the Commission

(c) aim to support hands-on and work-based training programmes aligned with the Union’s skills and workforce development objectives in the biotechnology and biomanufacturing sectors or in relation to enabling technologies, such as digital technologies, with specific applicability in biotechnology and biomanufacturing;

Amendment

(c) aim to support hands-on and work-based training programmes aligned with the Union’s skills and workforce development objectives in the biotechnology and biomanufacturing sectors or in relation to enabling technologies, such as ***non-animal and*** digital technologies, with specific applicability in biotechnology and biomanufacturing;

Amendment 48

Proposal for a regulation

Article 6 – paragraph 2 – point c

Text proposed by the Commission

(c) integrate quality, regulatory science, and safety testing functions supporting Union-wide development of advanced therapies;

Amendment

(c) integrate quality, regulatory science, and safety testing functions, ***prioritising the use of NAMs*** supporting Union-wide development of advanced therapies;

Amendment 49

Proposal for a regulation

Article 7 – paragraph 1

Text proposed by the Commission

1. Member States shall designate an authority (‘the designated authority’) responsible for assessing applications for recognition of health biotechnology strategic projects and high impact health biotechnology strategic projects.

Amendment

1. Member States shall designate an authority (‘the designated authority’) responsible for assessing applications for recognition of health biotechnology strategic projects and high impact health biotechnology strategic projects. ***The designated authority shall be able to assess all the selection criteria, particularly those related to compliance***

with ethical, environmental and social standards.

Amendment 50

Proposal for a regulation Article 11 – paragraph 4

Text proposed by the Commission

4. It shall coordinate the exchange of documents and information between the project promoters and the competent authorities and shall notify the promoter of the outcome of the decision-making process related to permit-granting, in accordance with national administrative arrangements. The authorities involved in the permit-granting process and other authorities concerned shall specify and make available to the single point of contact concerned the requirements and the scope of information requested of a project promoter.

Amendment

4. It shall coordinate the exchange of documents and information between the project promoters and the competent authorities and shall notify the promoter of the outcome of the decision-making process related to permit-granting, in accordance with national administrative arrangements. The authorities involved in the permit-granting process and other authorities concerned shall specify and make available to the single point of contact concerned the requirements and the scope of information requested of a project promoter. ***The single point of contact shall furthermore ensure that all relevant documents are made available upon request by the project promoter without prejudice to applicable legislation on confidential information.***

Amendment 51

Proposal for a regulation Article 11 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. The project promoter shall appoint one coordinator responsible for the project application and acting as contact point for the single point of contact of the Member State.

Amendment 52

Proposal for a regulation
Article 11 – paragraph 8

Text proposed by the Commission

8. Member States shall ensure that the single points of contact and all authorities involved in the permit-granting process have a sufficient number of qualified staff and adequate resources.

Amendment

8. Member States shall ensure that the single points of contact and all authorities involved in the permit-granting process have a sufficient number of qualified staff and adequate resources, ***to assess all relevant selection criteria, including those relating to ethical, environmental and social aspects of strategic projects.***

Amendment 53

Proposal for a regulation
Article 12 – paragraph 5

Text proposed by the Commission

5. Health biotechnology strategic projects ***shall*** also benefit, where applicable, from the tacit-approval in accordance with Article 14 and point II of the Annex to [COM Proposal 2025(984) for a Regulation on speeding-up environmental impact assessments – permitting regulation].

Amendment

5. Health biotechnology strategic projects ***may*** also benefit, where applicable, from the tacit-approval in accordance with Article 14 and point II of the Annex to [COM Proposal 2025(984) for a Regulation on speeding-up environmental impact assessments – permitting regulation].

Amendment 54

Proposal for a regulation
Article 13 – paragraph 1 – point c

Text proposed by the Commission

(c) assistance to inform the public and those in the vicinity of the project with the aim of increasing public acceptance of the project;

Amendment

(c) assistance to inform ***and consult*** the public ***within a reasonable timeframe*** and those in the vicinity of the project with the aim of increasing ***local consultations and public relevance and*** acceptance of the project;

Amendment 55

Proposal for a regulation
Article 14 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Health biotechnology strategic projects and high impact health biotechnology strategic projects benefiting from Member State or Union funding shall fully comply with Union and ethical, environmental and social legislation.

Amendment 56

Proposal for a regulation
Article 22 – paragraph 4 – point b a (new)

Text proposed by the Commission

Amendment

(ba) provide programmes to support the development, validation, standardisation, scale-up, market uptake and regulatory integration of NAMs across the full innovation and value chain;

Amendment 57

Proposal for a regulation
Article 56 – paragraph 1 – point 1
Regulation (EC) No 178/2002
Article 3 – paragraph 1 – point 19

Text proposed by the Commission

Amendment

19. ‘regulatory sandbox’ means a controlled environment where participants can test innovative products or substances ***and*** related processes as well as data and other regulatory requirements at a pre-market stage under a set of defined rules and monitoring and for a limited period of time;

19. ‘regulatory sandbox’ means a controlled environment where participants can test innovative products or substances, related processes ***or adapted regulatory solutions*** as well as data and other regulatory requirements at a pre-market stage under a set of defined rules and monitoring and for a limited period of time ***under regulatory supervision;***

Amendment 58

Proposal for a regulation

Article 56 – paragraph 1 – point 1

Regulation (EC) No 178/2002

Article 3 – paragraph 1 – point 20

Text proposed by the Commission

20. ‘regulatory sandbox plan’ means a plan setting out the scope, the requirements and the conditions governing the operation of a specific regulatory sandbox;

Amendment

20. ‘regulatory sandbox plan’ means a plan setting out ***the reasoning for the necessity to establish a regulatory sandbox, the objectives***, the scope, the requirements and the conditions governing the operation of a specific regulatory sandbox;

Amendment 59

Proposal for a regulation

Article 56 – paragraph 1 – point 2 a (new)

Regulation (EC) No 178/2002

Article 22 – paragraph 5 – point c a (new)

Text proposed by the Commission

Amendment

(2a) in Article 22(5), the following point is added:

‘(ca) advice or exploratory dialogue on the regulatory applicability of alternative approaches to animal testing, towards phasing out animal testing for chemical safety assessments and uptake of NAM, where scientifically validated and appropriate for the intended regulatory purpose, in accordance with Union legislation, while ensuring a high level of protection of human health, animal health and the environment and without lowering applicable safety standards.’

Amendment 60

Proposal for a regulation

Article 56 – paragraph 1 – point 2 b (new)

Regulation (EC) No 178/2002

Article 23 – paragraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(2b) *In Article 23, the following point is inserted:*

‘(fa) *to undertake action to promote the development and uptake of human-centred NAMs, as well as to cooperate with relevant bodies’;*

Amendment 61

Proposal for a regulation

Article 56 – paragraph 1 – point 3 – point a a (new)

Regulation (EC) No 178/2002

Article 28 – paragraph 4 – subparagraph 1 – point k a (new)

Text proposed by the Commission

Amendment

(aa) *in paragraph 4, the following point is inserted:*

‘(ka) *the panel on NAM’*

Amendment 62

Proposal for a regulation

Article 56 – paragraph 1 – point 3 – point b

Regulation (EC) No 178/2002

Article 28 – paragraph 6

Text proposed by the Commission

Amendment

6. The Scientific Committee and the Scientific Panels shall be chaired by the staff of the Authority *without the right to vote*. The Scientific Committee and the Scientific Panels shall *each choose two Vice-Chairs from among their members*.

6. The Scientific Committee and the Scientific Panels shall be chaired by *non-voting members of the Authority's staff. The Chair shall be responsible for the organization of the work, including setting agendas and timelines and ensuring compliance with the Rules of Procedure, while fully respecting the scientific independence of the Scientific Committee and the Scientific Panels. Members of the Authority's staff may provide scientific, technical and administrative support to the work of the Scientific Committee and the Scientific*

Panels, including contributing to the preparation of draft opinions, without prejudice to the exclusive responsibility of the members of the Scientific Committee and the Scientific Panels for the scientific content, conclusions and adoption of those opinions. The Scientific Committee and each Scientific Panel shall elect from among their members two Vice-Chairs and, where appropriate, scientific rapporteurs responsible for coordinating the preparation of draft opinions.

The staff of the Authority *chairing* the Scientific Committee and the Scientific Panels shall *be functionally independent from teams providing pre-submission advice under Article 32a.*

Amendment 63

Proposal for a regulation

Article 56 – paragraph 1 – point 3 – point c

Regulation (EC) No 178/2002

Article 28 – paragraph 9 – point h

Text proposed by the Commission

(h) the role of the Authority when chairing the Scientific Committee and the Scientific Panels.

Amendment

(h) the role of the Authority when chairing the Scientific Committee and the Scientific Panels *as well as the measures and safeguards therein to ensure independence and prevent conflicts of interest.*

Amendment 64

Proposal for a regulation

Article 56 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32a – paragraph 1

Text proposed by the Commission

1. Where Union law contains provisions for the Authority to provide a scientific output, including a scientific

Amendment

1. Where Union law contains provisions for the Authority to provide a scientific output, including a scientific

opinion, the Authority shall, at the request of a potential applicant or notifier, provide advice on the content of the application or notification, prior to its submission, including the rules applicable to and the required content thereof as well as on the design of the studies and testing strategies to support such an application or notification. Such advice provided by the Authority shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the Scientific Panels.

opinion, the Authority shall, at the request of a potential applicant or notifier, provide advice on the content of the application or notification, prior to its submission, including the rules applicable to and the required content thereof as well as on the design of the studies and testing strategies to support such an application or notification, ***with a view to facilitating high-quality applications, and with particular attention to SMEs, first-time applicants and applicants developing innovative technologies requiring novel evidence-generation approaches.*** Such advice provided by the Authority ***in a transparent, impartial and non-discriminatory manner*** shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the Scientific Panels.

To preserve the integrity of the work and activities of the Authority, as a general rule, the staff of the Authority providing the pre-submission support shall not be involved in the risk assessment of the specific application or notification that is the subject of the advice. In situations where specific expertise is required and can be provided only by the same staff, which would normally disqualify or limit their involvement, those individuals may participate where their expertise is necessary, subject to a documented declaration of interests and appropriate internal safeguards, provided they do not chair the relevant panel or take part in the adoption of the opinion. To ensure this separation of tasks, the Agency shall have all additional resources needed to implement this, equivalent to 28 full-time employees.

Amendment 65

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49a – paragraph 2 – subparagraph 1 – introductory part

Text proposed by the Commission

Amendment

Regulatory sandboxes may be established in relation to the following:

Regulatory sandboxes may be established in relation to the following, ***where pathways for controlled testing, notification or authorisation are not available or appropriate:***

Amendment 66

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49a – paragraph 2 – subparagraph 1 – point a

Text proposed by the Commission

Amendment

(a) all stages of the production, processing and distribution of food ***with the exception of novel foods***, and also of the feed produced for, or fed to food-producing animals;

(a) all stages of the production, processing and distribution of food, and also of the feed produced for, or fed to food-producing animals;

Amendment 67

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49a – paragraph 2 – subparagraph 2

Text proposed by the Commission

Amendment

The making available of products within a regulatory sandbox shall not be regarded as placing on the market.

The making available of products within a regulatory sandbox shall not be regarded as placing on the market. ***Where appropriate, the Commission or the Authority or both shall also recommend measures in order to mitigate any possible distortion of market conditions as a result of establishing a regulatory sandbox.***

Amendment 68

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49a – paragraph 3 – point c a (new)

Text proposed by the Commission

Amendment

(ca) supporting evidence-gathering and regulatory learning on safe and sustainable food and feed biotechnology, and innovative food production methods, with a view to reducing regulatory uncertainty and fostering consistent assessment pathways at Union level;

Amendment 69

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49a – paragraph 3 – point c b (new)

Text proposed by the Commission

Amendment

(cb) supporting the sharing of best practices through cooperation with the relevant public authorities;

Amendment 70

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49a – paragraph 3 – point c c (new)

Text proposed by the Commission

Amendment

(cc) facilitating and accelerating access to the Union market for innovative food and feed products, in particular those innovated or manufactured by SMEs, including start-ups and scale-ups;

Amendment 71

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49a – paragraph 5

Text proposed by the Commission

5. A participant to an established regulatory sandbox shall immediately inform the competent authorities of the Member State(s) concerned if it considers or has reason to believe that the conditions of the regulatory sandbox plan have not been complied with and/or there are potential risks to public health, animal health or welfare, plant health **or to** the environment, which may require the revocation of the regulatory sandbox or the amendment of the regulatory sandbox plan to provide for mitigating measures. Participants shall also immediately inform the competent authorities of any other information that concerns the quality, safety or efficacy of the subject matter of the relevant regulatory sandbox.

Amendment

5. A participant to an established regulatory sandbox shall immediately inform the competent authorities of the Member State(s) concerned if it considers or has reason to believe that the conditions of the regulatory sandbox plan have not been complied with and/or there are potential risks to public health, animal health or welfare, plant health, the environment, **consumer protection, biosecurity, including the risk of intentional misuse**, which may require the revocation of the regulatory sandbox or the amendment of the regulatory sandbox plan to provide for mitigating measures. Participants shall also immediately inform the competent authorities of any other information that concerns the quality, safety or efficacy of the subject matter of the relevant regulatory sandbox.

Amendment 72

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49a – paragraph 10

Text proposed by the Commission

10. A Member State may prolong the duration **once** of a regulatory sandbox for a limited time where this is justified by the need to attain the objective of the specific regulatory sandbox at hand and shall inform the Commission, the Authority and the other Member States thereof.

Amendment

10. A Member State may prolong the duration of a regulatory sandbox **once** for a limited time where this is **duly** justified by the need to attain the objective of the specific regulatory sandbox at hand and shall inform the Commission, the Authority and the other Member States thereof.

Amendment 73

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49a – paragraph 11 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Those acts shall not replace a Member State decision to establish a sandbox in their country, and shall not provide for the establishment of a regulatory sandbox without the agreement of the Member State concerned and shall not derogate from the requirements of Regulation (EU) 2015/2283 and Regulation (EU) No 1169/2011, traceability requirements and general food safety requirements.

Amendment 74

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49a a (new)

Text proposed by the Commission

Amendment

Article 49aa

Recommendation for the establishment of regulatory sandboxes at Union level

1. The Authority may, on its own initiative or upon request by the Commission or one or more Member State(s), issue a scientific recommendation to the Commission for the establishment of a regulatory sandbox where pathways for controlled testing, notification or authorisation are not available or appropriate:

(a) all stages of the production, processing and distribution of food, and also of the feed produced for, or fed to food-producing animals;

(b) food contact materials, with the exception of plastic recycled materials;

(c) products, other than food and feed, containing or consisting of genetically modified organisms as defined in Article 2, point (2), of Directive 2001/18/EC. The making available of products within a regulatory sandbox shall not be regarded as placing on the market. Where appropriate, the Commission or the Authority or both shall also recommend measures in order to mitigate any possible distortion of market conditions as a result of establishing a regulatory sandbox.

The existence of an authorisation pathway under the Regulation (EU) 2015/2283 shall not, in duly justified cases, preclude their inclusion in a regulatory sandbox, provided that the sandbox is intended solely to generate scientific evidence, support regulatory learning or the development of appropriate assessment methodologies, or reduce scientific uncertainty, without replacing or prejudging the authorisation procedure established under that Regulation and while ensuring a high level of protection of human health and consumers;

2. Where the Commission deems it appropriate to establish a regulatory sandbox, it shall communicate to the Member States a draft regulatory sandbox plan, which shall contain the following elements:

(a) the objectives of the regulatory sandbox;

(b) a description of the specific areas that the sandbox will cover, including the products or substances, processes, technologies and practices;

(c) a clearly defined geographical scope;

(d) a clearly defined and limited temporal scope;

(e) the regulatory or scientific justifications for setting up the regulatory sandbox including a justification as to why the pathways for controlled testing,

notification or authorisation are not available or appropriate;

(f) an identification of the relevant provisions of Union law that apply for the purposes of the regulatory sandbox and those that do not apply or are adapted;

(g) the procedure for the application and selection for participants, including clearly defined eligibility criteria, the modalities governing the provision of the explicit and prior consent from participating final consumers as well as the modalities by which the participants may end their participation;

(h) the involvement of the Authority, other Union agencies and national agencies, where relevant, provided that they have expressed interest to join the regulatory sandbox;

(i) the activities allowed to be carried out and the conditions, requirements and safeguards that apply;

(j) an assessment that identifies how potential risks to public health, animal health or welfare, plant health or the environment are eliminated or mitigated;

(k) details on how activities will be monitored, including responsibilities of the competent authorities entrusted with the supervision of the implementation of the sandbox plan

3. On the basis of the recommendation of the Authority, the Commission may, by means of implementing acts, establish a regulatory sandbox at Union level or authorise the coordinated establishment of a multinational regulatory sandbox by participating Member States. Prior to adopting an implementing act pursuant to paragraph 3, the Commission shall consult the Member States taking into account the recommendation of the Authority and the sandbox plan pursuant to paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in

Article 51.

4. Regulatory sandboxes established pursuant to this Article shall be subject to periodic monitoring and evaluation. The Authority shall submit to the Commission a report on the operation and outcomes of the sandbox, including any implications for food and feed safety, human health, animal health and the environment.

5. The Commission shall be empowered to adopt implementing acts laying down detailed rules for the operation, supervision, monitoring, suspension and termination of regulatory sandboxes established pursuant to this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51.

6. Those acts referred in paragraphs 3 and 5 shall not replace a Member State decision to establish a sandbox in their country, shall not provide for the establishment of a regulatory sandbox without the agreement of the Member State concerned and shall not derogate from the requirements of Regulation (EU) 2015/2283 and Regulation (EU) No 1169/2011, traceability requirements and general food safety requirements.

Amendment 75

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49b – title

Text proposed by the Commission

Establishment of regulatory sandboxes

Amendment

Establishment of regulatory sandboxes **by Member States**

Amendment 76

Proposal for a regulation

Article 56 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 49b – paragraph 1 – point e

Text proposed by the Commission

(e) the regulatory or scientific justifications for setting up the regulatory sandbox;

Amendment

(e) the regulatory or scientific justifications for setting up the regulatory sandbox, ***including a justification as to why the pathways for controlled testing, notification or authorisation are not available or appropriate, the existence of an authorisation pathway under the Regulation (EU) 2015/2283 shall not, in duly justified cases, preclude their inclusion in a regulatory sandbox, provided that the sandbox is intended solely to generate scientific evidence, support regulatory learning or the development of appropriate assessment methodologies, or reduce scientific uncertainty, without replacing or prejudging the authorisation procedure established under that Regulation and while ensuring a high level of protection of human health and consumers;***

Amendment 77

Proposal for a regulation
Article 56 – paragraph 1 – point 7
Regulation (EC) No 178/2002
Article 49b – paragraph 1 – point g

Text proposed by the Commission

(g) the procedure for the application and selection for participants, including clearly defined eligibility criteria, the modalities governing the provision of the explicit and prior consent from participating final consumers as well as the modalities by which the participants may end their participation;

Amendment

(g) the procedure for the application and selection for participants, including clearly defined eligibility criteria, the modalities governing the provision of the explicit and prior consent from participating final consumers, ***set out in clear, comprehensible language, specifying that the product is available solely in the context of the regulatory sandbox,*** as well as the modalities by which the participants may end their

participation;

Amendment 78

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49b – paragraph 1 – point h a (new)

Text proposed by the Commission

Amendment

(ha) the involvement of the Authority, other Union agencies and national agencies, where relevant, provided that they have expressed interest to join the regulatory sandbox;

Amendment 79

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49b – paragraph 1 – point i

Text proposed by the Commission

Amendment

(i) the activities allowed to be carried out and the conditions **and** requirements that apply;

(i) the activities allowed to be carried out and the conditions, and requirements **and safeguards** that apply;

Amendment 80

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49b – paragraph 1 – point j

Text proposed by the Commission

Amendment

(j) an assessment that identifies how potential risks to public health, animal health or welfare, plant health or the environment **are** mitigated;

(j) an assessment that identifies how potential risks to public health, animal health or welfare, plant health or the environment, **consumer protection and biosecurity are eliminated or** mitigated;

Amendment 81

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49b – paragraph 1 – point k

Text proposed by the Commission

(k) details on how activities will be monitored, including responsibilities of the competent authorities entrusted with the supervision of the implementation of the sandbox plan.

Amendment

(k) details on how activities will be monitored, including responsibilities of the competent authorities entrusted with the supervision of the implementation of the sandbox plan, ***and corresponding reporting and exchange of information to the Commission and the Authority as well as, as appropriate, the corrective actions to be taken and the arrangements for organising and financing supervision.***

Amendment 82

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49b – paragraph 1 – point k a (new)

Text proposed by the Commission

Amendment

(ka) in the case of food – specific conditions for labelling, traceability and documenting final consumer consent.

Amendment 83

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49b – paragraph 3

Text proposed by the Commission

Amendment

3. Member States shall engage with relevant stakeholders during the preparation of a draft regulatory sandbox plan to gather diverse perspectives and

3. Member States shall engage with relevant stakeholders, ***including civil society representatives, trade unions and non-governmental organisations*** during the preparation of a draft regulatory

foster collaboration.

sandbox plan to gather diverse perspectives and foster collaboration.

In the case of food or feed-related sandboxes, those reports shall also include non-confidential information on the number and type of products tested, final consumer participation, reported adverse reactions, corrective measures, suspended or completed testing, and conclusions relevant for future data requirements and risk assessment. Those reports shall be made publicly available by the Commission, while respecting trade secrets and the protection of personal data.

Amendment 84

Proposal for a regulation

Article 57 – paragraph 1 – point 2

Regulation (EC) No 1394/2007

Article 4a – paragraph 1 – introductory part

Text proposed by the Commission

1. By way of exemption from Article 5a of Regulation (EU) No 536/2014 [as added by the revised Regulation No (EC) 726/2004], sponsors of clinical trials that concern advanced therapy investigational medicinal products as defined in Article 2(7) of that Regulation, consisting or containing GMOs, are not required to submit an environmental risk assessment, if those products belong to at least one of the following categories:

Amendment

1. By way of exemption from Article 5a of Regulation (EU) No 536/2014 [as added by the revised Regulation No (EC) 726/2004], sponsors of clinical trials that concern advanced therapy investigational medicinal products as defined in Article 2(7) of that Regulation, consisting or containing GMOs, are not required to submit an environmental risk assessment, if those products belong to at least one of the following categories, ***and provided they present no or a negligible risk to human health, animal health, ecosystems and the environment.***

Amendment 85

Proposal for a regulation

Article 57 – paragraph 1 – point 2

Regulation (EC) No 1394/2007

Article 4a – paragraph 1 – point d

Text proposed by the Commission

(d) genetic material altered using genome editing techniques (ex vivo or in vivo), ***provided that it has generally negligible adverse effects on human health and the environment.***

Amendment

(d) genetic material altered using genome editing techniques (ex vivo or in vivo);

Amendment 86

Proposal for a regulation

Article 57 – paragraph 1 – point 2

Regulation (EC) No 1394/2007

Article 4a – paragraph 2

Text proposed by the Commission

2. The exemption provided for in paragraph 1 of this Article is subject to the sponsor submitting, through the EU Portal and as part of the clinical trial application dossier, a reasoned ***declaration*** confirming that the advanced investigational therapy medicinal product concerned falls into one or more of the categories referred to in points (a) to (d) of paragraph 1, of this Article. The Committee for Medicinal Products for Human Use (CHMP) referred to in Article [148] of Regulation [...] [revised Regulation No (EC) 726/2004] shall verify this declaration and the reasons provided, and the CHMP may, to this end, access the information on the clinical trial application in the EU portal. The CHMP shall communicate its opinion on the declaration to the sponsor and to the reporting Member State within 21 days after the submission date referred to in Article 5(1) of Regulation (EU) No 536/2014 [as revised by European Biotech Act].

Amendment

2. The exemption provided for in paragraph 1 of this Article is subject to the sponsor submitting, through the EU Portal and as part of the clinical trial application dossier, a reasoned ***justification*** confirming that the advanced investigational therapy medicinal product concerned falls into one or more of the categories referred to in points (a) to (d) of paragraph 1, of this Article ***and present no or a negligible risk to human health, animal health, ecosystems and the environment.*** The Committee for Medicinal Products for Human Use (CHMP) referred to in Article [148] of Regulation [...] [revised Regulation No (EC) 726/2004] shall verify this declaration and the reasons provided, and the CHMP may, to this end, access the information on the clinical trial application in the EU portal. The CHMP shall communicate its opinion on the declaration to the sponsor and to the reporting Member State within 21 days after the submission date referred to in Article 5(1) of Regulation (EU) No 536/2014 [as revised by European Biotech Act].

Amendment 87

Proposal for a regulation

Article 59 – paragraph 1 – point 1

Regulation (EU) 2019/6

Article 3 – paragraph 3

Text proposed by the Commission

The Union GMO legislation shall not apply to veterinary medicinal products containing or consisting of genetically modified organisms that are authorised or manufactured in accordance with this Regulation. The administration of veterinary medicinal products shall not bring the treated animal or **their** products under the scope of the GMO rules.

Amendment

Union GMO legislation shall not apply to veterinary medicinal products containing or consisting of genetically modified organisms that are authorised or manufactured in accordance with this Regulation, ***provided that the environmental risk assessment required under Article 9(2a) of this Regulation has been carried out.*** The administration of ***such*** veterinary medicinal products ***in accordance with the terms of the marketing authorisation*** shall not, ***in itself***, bring the treated animal or products ***derived from it*** under the scope of the GMO rules. ***This paragraph is without prejudice to the requirements applicable to food and feed derived from treated animals under Regulation (EC) No 1829/2003 and Regulation (EC) No 178/2002.***

Amendment 88

Proposal for a regulation

Article 59 – paragraph 1 – point 4 – point a

Regulation (EU) 2019/6

Article 9 – paragraph 2a

Text proposed by the Commission

2a. In case of clinical trials with veterinary medicinal products containing or consisting of genetically modified organisms, the competent authorities shall assess potential adverse effects on human health and the environment, having regard to the specific characteristics of the product and in accordance with the principles for environmental risk assessment set out in Annex II. ***Where appropriate, the implementation of risk mitigation***

Amendment

2a. In case of clinical trials with veterinary medicinal products containing or consisting of genetically modified organisms, the competent authorities shall assess potential adverse effects on human health, ***animal health*** and the environment, having regard to the specific characteristics of the product, ***including persistence, shedding, transmission potential and the need for proportionate risk-mitigation measures,*** and in accordance with the

measures shall be required.

principles for environmental risk assessment set out in Annex II. ***Risk-mitigation*** measures shall be required ***where the assessment identifies a risk to human health, animal health or the environment.***

Amendment 89

Proposal for a regulation

Article 59 – paragraph 1 – point 4 – point b

Regulation (EU) 2019/6

Article 9 – paragraph 3 – subparagraph 2

Text proposed by the Commission

During this period, where the trial concerns a veterinary medicinal product containing or consisting of genetically modified organisms, the competent authorities ***may*** consult with the bodies set up by the Union or Member States in accordance with ***under*** Directive 2001/18/EC, in particular in case of novel questions or ***first-in-class*** veterinary medicinal products. The consulted bodies shall ensure protection of commercially confidential information and security of exchange of information.

Amendment

During this period, where the trial concerns a veterinary medicinal product containing or consisting of genetically modified organisms, the competent authorities ***shall*** consult with the bodies set up by the Union or Member States in accordance with Directive 2001/18/EC, in particular in case of novel questions or ***first-in-class*** veterinary medicinal products. ***Such consultation shall be proportionate, risk-based and subject to clear timelines.*** The consulted bodies shall ensure protection of commercially confidential information and security of exchange of information.

Amendment 90

Proposal for a regulation

Article 59 – paragraph 1 – point 5

Regulation (EU) 2019/6

Article 28 – paragraph 2

Text proposed by the Commission

During the process of examination of applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms, the Agency may hold consultations with the bodies set up by the Union or Member States in accordance

Amendment

During the process of examination of applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms, the Agency may hold consultations with the bodies set up by the Union or Member States in accordance

with Directive 2001/18/EC, in particular for first-in-class products or when a novel question arises. The consulted bodies shall ensure protection of commercially confidential information and security of exchange of information.

with Directive 2001/18/EC, in particular for first-in-class products or when a novel question arises. ***Such consultation shall be proportionate, risk-based and subject to clear timelines.*** The consulted bodies shall ensure protection of commercially confidential information and security of exchange of information.

Amendment 91

Proposal for a regulation

Article 59 – paragraph 1 – point 6 a (new)

Regulation (EU) 2019/6

Article 40a a (new)

Text proposed by the Commission

Amendment

(6a) The following Article is inserted:

‘Article 40aa

‘One Health’ priority product designation

1. A veterinary medicinal product that is designed for the prevention, treatment or control of a zoonotic disease of significant public health relevance may, upon application by the developer be designated as a ‘One Health’ Priority Product, in accordance with the criteria laid down in this Regulation.

2. A veterinary medicinal product designated as a ‘One Health’ Priority Product shall be eligible to benefit from the following support measures:

(a) priority scientific advice and enhanced regulatory support from the competent Union authorities;

(b) accelerated authorisation procedures, where the conditions established under the applicable Union legislation are fulfilled;

(c) a reduction fees, in accordance with the applicable Union legal framework; and

(d) priority consideration within the

instruments managed by the Health Emergency Preparedness and Response Authority (HERA).

3. The designation of a veterinary medicinal product as a ‘One Health’ Priority Product shall not affect the requirements relating to its quality, safety and efficacy under applicable Union legislation, nor shall it confer any exclusive rights beyond those expressly provided for in this Regulation.’

Amendment 92

Proposal for a regulation

Article 59 – paragraph 1 – point 8

Regulation (EU) 2019/6

Article 136a – paragraph 1 – point a

Text proposed by the Commission

(a) it can be expected that those technologies, methods or products will have a positive impact on animal health without **unacceptable** negative impacts on human health or the environment;

Amendment

(a) it can be expected that those technologies, methods or products will have a positive impact, **based on available scientific evidence**, on animal health without negative impacts on human health or the environment;

Amendment 93

Proposal for a regulation

Article 59 – paragraph 1 – point 8

Regulation (EU) 2019/6

Article 136a – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Priority may be given to applications addressing zoonotic diseases, transboundary animal diseases, antimicrobial resistance or major unmet animal-health needs with direct relevance for public health or food security.

ANNEX: DECLARATION OF INPUT

Pursuant to Article 8 of Annex I to the Rules of Procedure, the rapporteur for opinion declares that he included in his opinion input on matters pertaining to the subject of the file that he received, in the preparation of the opinion, prior to the adoption thereof in committee, from the following interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register¹, or from the following representatives of public authorities of third countries, including their diplomatic missions and embassies:

1. Interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register
Hipra SA
Novo Nordisk A/S
Amgen Inc.
Medicines for Europe
Biocat – Bioregió de Catalunya
European Association for Bioindustries - Europabio
Asociación Española Empresas Biotecnología - Asebio
Asociación Española de Biosimilares - BioSim
2. Representatives of public authorities of third countries, including their diplomatic missions and embassies
-

The list above is drawn up under the exclusive responsibility of the rapporteur for opinion.

Where natural persons are identified in the list by their name, by their function or by both, the rapporteur for opinion declares that he has submitted to the natural persons concerned the European Parliament's Data Protection Notice No 484 (<https://www.europarl.europa.eu/data-protect/index.do>), which sets out the conditions applicable to the processing of their personal data and the rights linked to that processing.

¹ Interinstitutional Agreement of 20 May 2021 between the European Parliament, the Council of the European Union and the European Commission on a mandatory transparency register (OJ L 207, 11.6.2021, p. 1, ELI: http://data.europa.eu/eli/agree_interinst/2021/611/oj).

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	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)	
References	COM(2025)1022 – C10-0363/2025 – 2025/0406(COD)	
Committee(s) responsible Date announced in plenary	SANT 18.5.2026	ITRE 18.5.2026
Opinion by Date announced in plenary	ENVI 18.5.2026	
Rapporteur for opinion Date appointed	Nicolás González Casares 9.3.2026	
Discussed in committee	23.6.2026	
Date adopted	1.10.2026	
Result of final vote	+: 53 –: 11 0: 5	

FINAL VOTE BY ROLL CALL BY THE COMMITTEE ASKED FOR OPINION

53	+
PPE	Peter Agius, Pascal Arimont, Zala Černilec Tomašič, Dóra Dávid, Niels Flemming Hansen, Monika Hohlmeier, Radan Kanev, Stefan Köhler, Dolors Montserrat, Fernando Navarrete Rojas, Lídia Pereira, Sirpa Pietikäinen, Jessica Polfjård, Massimiliano Salini, Oliver Schenk, Susana Solís Pérez, Michał Szczerba, Ingeborg Ter Laak, Dimitris Tsodras, Bogdan Andrzej Zdrojewski
Renew	Stine Bosse, Sigrid Friis, Gerben-Jan Gerbrandy, Martin Hojsík, Vlad Vasile-Voiculescu, Emma Wiesner, Michał Wieszik
S&D	Sakis Arnaoutoglou, Christophe Clergeau, Annalisa Corrado, Nikolas Farantouris, Hélène Fritzon, Nicolás González Casares, Javi López, César Luena, Pierfrancesco Maran, Alessandra Moretti, Thomas Pellerin-Carlin, Elena Sancho Murillo, Marta Temido, Irene Tinagli, Bruno Tobback, Tiemo Wölken
The Left	Per Clausen, Martin Günther, Anja Hazekamp
Verts/ALE	Martin Häusling, Pär Holmgren, Ignazio Roberto Marino, Tilly Metz, Jutta Paulus, Majdouline Sbai, Lena Schilling

11	-
ECR	Paolo Insolvini
ESN	Anja Arndt, Marc Jongen, Volker Schnurrbusch
NI	Fernand Kartheiser
PfE	Mathilde Androuët, Barbara Bonte, Marie-Luce Brasier-Clain, Jorge Buxadé Villalba, Valérie Deloge, Viktória Ferenc

5	0
ECR	Beatrice Timgren, Laurence Trochu, Aurelijus Veryga, Anna Zalewska
NI	Ondřej Dostál

Key to symbols:

+ : in favour

- : against

0 : abstention