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Committee on Public Health
Committee on Industry, Research and Energy

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AMENDMENTS
858 - 1075

Draft report
Vytenis Povilas Andriukaitis, Wouter Beke
(PE789.987v01-00)

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)

Proposal for a regulation
(COM(2025)1022 – 2025/0406(COD))

Amendment 858
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 98

Text proposed by the Commission	*Amendment*
(98) Certain tools with a potential to be misused without further modification and to cause serious harm to public health and safety, agricultural crops and other plants, to animals, the environment, material or government security (dual-use research of concern - 'DURC') are increasingly affordable and accessible, also through progress in AI capabilities, which elevates the risk of misuse by actors lacking appropriate competence, oversight, legitimate or peaceful intent. A proportionate and risk-based framework is therefore necessary to minimise opportunities for misuse of DURC, including on AI models in biological applications, while preserving legitimate research and innovation.	(98) Certain tools with a potential to be misused without further modification and to cause serious harm to public health and safety, agricultural crops and other plants, to animals, the environment, material or government security (dual-use research of concern - 'DURC') are increasingly affordable and accessible, also through progress in AI capabilities, which elevates the risk of ***non-ethical use of AI and*** misuse by actors lacking appropriate competence, oversight, legitimate or peaceful intent. A proportionate and risk-based framework is therefore necessary to minimise opportunities for misuse of DURC, including on AI models in biological applications, while preserving legitimate research and innovation.

Or. en

Amendment 859
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 100

Text proposed by the Commission	*Amendment*
(100) The Commission should monitor Member States in the enforcement of this legislation, including by requesting information and records to check the screening and suspicious transaction reporting frameworks of economic operators.	(100) The Commission should monitor Member States in the enforcement of this legislation, including by requesting information and records to check the screening and suspicious transaction reporting frameworks of economic operators. ***To this end, close cooperation is needed between the Member States and the Commission to provide the necessary***

information, as required, on the measures taken to implement and ensure compliance with this Regulation, as well as on the effectiveness of national oversight and control mechanisms. Monitoring should allow the early identification of shortcomings, the exchange of best practices and should promote a uniform application of the rules throughout the Union. It should be proportionate and risk-based, avoiding unnecessary administrative costs for economic operators and the competent authorities and should respect Union data protection rules, the confidentiality of business information and the security of sensitive information.

Or. ro

Amendment 860
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 102

Text proposed by the Commission	*Amendment*
(102) AI offers significant potential to enhance the Union's competitiveness and innovation capacity, including in the area of biotechnology. This potential should be realised in a safe and responsible manner. In this regard, Regulation (EU) 2024/1689 lays down harmonised rules for placing on the market putting into service and use of AI systems and models in the Union, prohibitions of certain AI practices, harmonised transparency rules for certain AI systems, rules on market monitoring, market surveillance, governance and enforcement as well as measures to support innovation. AI systems and general-purpose AI models can lower the barrier for actors to misuse biotechnology. The provisions of Regulation (EU) 2024/1689 governing AI systems and general-purpose	(102) AI offers significant potential to enhance the Union's competitiveness and innovation capacity, including in the area of biotechnology. This potential should be realised in a safe***, ethical*** and responsible manner. In this regard, Regulation (EU) 2024/1689 lays down harmonised rules for placing on the market putting into service and use of AI systems and models in the Union, prohibitions of certain AI practices, harmonised transparency rules for certain AI systems, rules on market monitoring, market surveillance, governance and enforcement as well as measures to support innovation. AI systems and general-purpose AI models can lower the barrier for actors to misuse biotechnology. The provisions of Regulation (EU) 2024/1689 governing AI systems and general-purpose

AI models aim to mitigate this. Further, AI models, as described in Regulation (EU) 2024/1689, used in biological applications, that are not covered by Regulation (EU) 2024/1689 (‘AI models in biological applications’) can also pose risks, including different types of systemic biological risks.	AI models aim to mitigate this. Further, AI models, as described in Regulation (EU) 2024/1689, used in biological applications, that are not covered by Regulation (EU) 2024/1689 (‘AI models in biological applications’) can also pose risks, including different types of systemic biological risks.

Or. en

Amendment 861
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 105

Text proposed by the Commission	*Amendment*
(105) The European ***Health*** Biotechnology Steering Group established by this Regulation should also ensure proper coordination and information exchanges among Member States on the enforcement of the biosecurity provisions in this Regulation, consulting the Advisory Group, other relevant existing bodies and external experts where appropriate.	(105) The European Biotechnology Steering Group established by this Regulation should also ensure proper coordination and information exchanges among Member States on the enforcement of the biosecurity provisions in this Regulation, consulting the Advisory Group, other relevant existing bodies and external experts where appropriate.

Or. en

Amendment 862
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 105 a (new)

Text proposed by the Commission	*Amendment*
	(105a) The effective and coherent implementation of this Regulation depends on adequately resourced Union scientific and regulatory capacity. The Commission should ensure that the relevant Union agencies and bodies, including the European Medicines

Agency, the European Centre for Disease Prevention and Control, the European Food Safety Authority, the European Chemicals Agency, the European Environment Agency and the European Defence Agency, have the necessary resources to support the implementation of this Regulation within their respective mandates. The Commission should also promote structured cooperation and regular exchange between those agencies and bodies, within their respective mandates, in order to ensure coherent scientific advice, avoid unnecessary duplication and administrative burden, identify cross-sector risks and support coordinated regulatory preparedness for biotechnology applications.

Or. en

Amendment 863
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 106

Text proposed by the Commission	*Amendment*
(106) This Regulation should establish a framework of measures, in particular for health biotechnology strategic projects and high impact health biotechnology strategic projects, to ensure the growth of the health biotechnology sector. This Regulation and, in particular, the measures in Chapters II to VIII, should serve the aim of creating and reinforcing favourable conditions for health biotechnology, from research and development to the timely placing on the Union market and production of biotechnology innovations and products. The pathway to placing on the the market of health biotechnology innovations and products are governed by important and comprehensive sets of regulatory rules and procedures. Reviewing ***and*** streamlining	(106) This Regulation should establish a framework of measures, in particular for health biotechnology strategic projects and high impact health biotechnology strategic projects, to ensure the growth of the health biotechnology sector ***that contributes to public health, resilience, sustainability and equitable access, while preserving the high standards of quality, safety and efficacy laid down in Union law***. This Regulation and, in particular, the measures in Chapters II to VIII, should serve the aim of creating and reinforcing favourable conditions for health biotechnology, from research and development to the timely placing on the Union market and production of biotechnology innovations and products ***while maintaining Union***

these rules and procedures ***is an inherent part to achieve the aim of*** facilitating and accelerating the development, placing on the market and production of health biotechnology innovations and products. The practical effectiveness of the measures of this Regulation, in particular those in Chapters II to VIII, depends ***to a large extent on a review and streamlining of certain rules and*** procedures ***applicable to health biotechnology innovations and products*** so as to facilitate timely access to the market. ***As set out in recitals [5 to 7], health biotechnology must be understood broadly and encompasses also the veterinary and phytosanitary fields which have as their direct objective the protection of public health.***

standards and ensuring that innovation serves the public interest. The pathway to placing on the the market of health biotechnology innovations and products are governed by important and comprehensive sets of regulatory rules and procedures. Reviewing***, improving and, where appropriate,*** streamlining ***regulatory*** procedures ***while maintaining a high level of protection of human health, animal health and the environment may contribute to*** facilitating and accelerating the development, placing on the market and production of health biotechnology innovations and products. The practical effectiveness of the measures of this Regulation, in particular those in Chapters II to VIII, ***also*** depends ***on ensuring that applicable regulatory*** procedures ***are coherent, efficient, predictable and proportionate, while maintaining the objectives and requirements of Union legislation*** so as to facilitate timely access to the market.

Or. en

Justification

Europe's biotech strategy should balance competitiveness and innovation with timely, affordable patient access and the long-term sustainability of public healthcare.

Amendment 864
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 106

Text proposed by the Commission	*Amendment*
(106) This Regulation should establish a framework of measures, in particular for health biotechnology strategic projects and high impact health biotechnology strategic projects, to ensure the growth of the health biotechnology ***sector***. This Regulation and, in particular, the measures in Chapters II to VIII, should serve the aim of creating and	(106) This Regulation should establish a framework of measures, in particular for health biotechnology strategic projects and high impact health biotechnology strategic projects, to ensure the growth of the health biotechnology ***and biomanufacturing sectors, in particular in the area of health***. This Regulation and, in particular, the

reinforcing favourable conditions for health biotechnology, from research and development to the timely placing on the Union market and production of biotechnology innovations and products. The pathway to placing on the the market of health biotechnology innovations and products are governed by important and comprehensive sets of regulatory rules and procedures. Reviewing and streamlining these rules and procedures is an inherent part to achieve the aim of facilitating and accelerating the development, placing on the market and production of health biotechnology innovations and products. The practical effectiveness of the measures of this Regulation, in particular those in Chapters II to VIII, depends to a large extent on a review and streamlining of certain rules and procedures applicable to health biotechnology innovations and products so as to facilitate timely access to the market. As set out in recitals [5 to 7], health biotechnology must be understood broadly and encompasses also the veterinary and phytosanitary fields which have as their direct objective the protection of public health.

measures in Chapters II to VIII, should serve the aim of creating and reinforcing favourable conditions for health biotechnology, from research and development to the timely placing on the Union market and production of biotechnology innovations and products. The pathway to placing on the the market of health biotechnology innovations and products are governed by important and comprehensive sets of regulatory rules and procedures. Reviewing and streamlining these rules and procedures is an inherent part to achieve the aim of facilitating and accelerating the development, placing on the market and production of health biotechnology innovations and products. The practical effectiveness of the measures of this Regulation, in particular those in Chapters II to VIII, depends to a large extent on a review and streamlining of certain rules and procedures applicable to health biotechnology innovations and products so as to facilitate timely access to the market. As set out in recitals [5 to 7], health biotechnology must be understood broadly and encompasses also the veterinary and phytosanitary fields which have as their direct objective the protection of public health.

Or. en

Amendment 865
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 106 a (new)

Text proposed by the Commission	*Amendment*
	(106a) Developers of innovative biopharmaceuticals make decisions on the location of clinical trials and manufacturing several years before eligibility for the extension provided for in Article 27 can be assessed, at a point in the financing cycle, typically the

transition between mid-stage and late-stage venture financing, where access to capital in the Union is most constrained. Enabling the Agency to issue, at the developer's request, an early non-binding scientific opinion on whether the novelty and clinical trial location conditions are likely to be met would allow the value of a potential extension to be reflected in investment decisions at that critical stage, thereby strengthening the incentive to conduct development, trials and manufacturing in the Union without altering the conditions of eligibility or the final assessment carried out at the time of marketing authorisation.

Or. en

Justification

This recital supports the proposed changes made to Article 27. It gives the rationale as to why the "SPC Candidate Status" certificate will be valuable to developers by sending investment signals to capital markets.

Amendment 866
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Recital 108 a (new)

Text proposed by the Commission	*Amendment*
	(108a) The EU is firmly committed to phasing out animal testing at the earliest opportunity. This policy goal recognises the need to protect animals as sentient beings; it is not only an ethical imperative but also an opportunity for industrial competitiveness. As recognised in the Commissions Roadmap towards phasing out animal testing for chemical safety assessments, the European Medicines Agency (EMA) provides the most advanced model among the decentralised EU agencies, aligned with the safe-space concept through initiatives such as the Innovation Task Force, voluntary data

submission ('safe harbour'), scientific advice and qualification procedures. The Authority, on the other hand, although it offers general pre-submission and helpdesk support, it lacks mechanisms to provide scientific advice on alternative approaches or exploratory dialogue on their regulatory applicability. It is therefore appropriate to strengthen the Authority's mandate to ensure it can undertake action to promote the uptake of human-centered NAMs, offer advice on the regulatory applicability of alternative approaches to animal testing, and to set up a dedicated panel on New Approach Methodologies.

Or. en

Amendment 867
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Recital 109

Text proposed by the Commission	*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.	(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 give particular attention to the assessment of foods high in fat, sugar or salt (HFSS), as well as ultra-processed foods (UPFs), given their documented impact on public health. The Authority should ensure that its scientific advice takes due account of the Union's public-health objectives, including the promotion of healthier diets and the prevention of non-communicable diseases.***

Or. en

Amendment 868
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 109

Text proposed by the Commission	*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.	(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 carrying out this mandate, the Authority should pay particular attention to foods high in fat, sugar or salt (HFSS), as well as ultra-processed foods (UPFs), in light of their well-documented impact on public health. The Authority should ensure that its scientific advice fully reflects the Union's public health objectives, including the promotion of healthier diets and the prevention of non-communicable diseases.***

Or. en

Justification

While we do not support the inclusion of food policy within the scope of the Biotech Act, strengthening EFSA's nutrition mandate remains important. EFSA should prioritise the scientific assessment of foods high in fat, sugar or salt and ultra-processed foods, given their well-established impact on public health. This would support healthier diets, the prevention of non-communicable diseases and stronger consumer protection, within EFSA's existing mandate.

Amendment 869
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 109

Text proposed by the Commission	*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.	(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. ***The Authority should particularly pay attention that the scientific advice provided takes the Unions objective to prevent non-communicable dieases and promte healthier diets into account.***

Or. en

Amendment 870
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 109 a (new)

Text proposed by the Commission	*Amendment*
	(109a) As an increasing number of foods placed on the Union market bear nutrition and health claims, indicating or suggesting that they possess particular nutritional properties or that their consumption is associated with specific health benefits, it is appropriate to ensure a high level of scientific scrutiny of such claims. The Authority should therefore be responsible for verifying the scientific substantiation of nutrition and health claims submitted in accordance with Regulation (EC) No 1924/2006 of the European Parliament and of the Council. Such verification should ensure that only claims supported by generally accepted scientific evidence and fulfilling the requirements laid down in that Regulation

are authorised for use within the Union.

Or. en

Amendment 871
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 109 b (new)

Text proposed by the Commission	*Amendment*
	(109b) Experience gained in the implementation of Regulation (EC) No 1924/2006 has revealed shortcomings in the current system for the scientific assessment of nutrition and health claims. In particular, consumers continue to be exposed to nutrition and health claims relating to foods with poor nutritional compositions and to certain health claims that have not been subject to a complete scientific assessment, thereby undermining the objective of ensuring a high level of consumer protection and enabling consumers to make informed choices. It is therefore appropriate to strengthen the role of the Authority in the scientific evaluation of nutrition and health claims and to ensure that its assessments contribute effectively to the Union's public health objectives and counters marketing practices by the industry to circumvent the Regulation 1924/2006 on nutrition and health claims made on foods.

Or. en

Amendment 872
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 109 c (new)

Text proposed by the Commission	*Amendment*
	(109c) Children and adolescents constitute a particularly vulnerable group of consumers and continue to be exposed to extensive advertising and marketing of processed foods high in fat, sugar and salt across broadcast and digital media. In order to ensure a high level of consumer protection and to contribute to the prevention of diet-related non-communicable diseases, renewed attention should be given to establishing an effective and Union-wide approach to reducing such exposure. The Commission, in cooperation wih the Agency, should therefore consider enforcing legislative measures to strengthen the protection of children and adolescents from the marketing of foods that are inconsistent with the Union's public health objectives.

Or. en

Amendment 873
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Recital 110

Text proposed by the Commission	*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	(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.

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. ***The Union may establish regulatory dialogue platforms pursuant to Article 32a(2) to complement pre-submission advice through structured dialogue, dossier preparation tools and joint training.*** 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.

Or. en

Amendment 874
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 110

Text proposed by the Commission	*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	(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.

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. ***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.

Or. en

Amendment 875
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Recital 110

Text proposed by the Commission	*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.	(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***, however the person giving the pre-submission advice should not be involved in assessing the final application***. 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.

Or. en

Amendment 876
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 110 a (new)

Text proposed by the Commission	*Amendment*
	(110a) In order to fulfil its expanded advisory functions, the Authority should be provided with adequate financial, technical and human resources to enable it to perform its tasks effectively. Particular attention should be paid to preserving and strengthening the Authority's scientific expertise, independence and capacity to deliver high-quality, evidence-based scientific advice in a timely manner. The resources made available to the Authority should therefore correspond to its expanded responsibilities under this Regulation, whilst ensuring that its scientific excellence, independence and advisory capacity are maintained.

Or. en

Amendment 877
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Recital 111

Text proposed by the Commission	*Amendment*
(111) Practice has shown that the existing procedural consequences in the event of non-compliance with the notification requirement of commissioned studies at pre-submission phase appear to be too severe, particularly for small and medium-sized enterprises, and could impede competitiveness and innovation in	***deleted***

the food chain. It is therefore necessary to shorten the existing procedural consequence in the event of non-compliance from six months to three months following the re-submission of the relevant application or notification.

Or. en

Amendment 878
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 113

Text proposed by the Commission	*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 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 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.	***deleted***

Or. en

Amendment 879
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Recital 113

Text proposed by the Commission	*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 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 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.***	(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 promoting resource efficiency and waste reduction. It is therefore appropriate to ***guarantee proper risks assessments and risk management***.

Or. en

Amendment 880
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 113

Text proposed by the Commission	*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 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 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	(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 regulatory sandboxes***, where pathways for controlled testing, notification or authorisation are not available or appropriate,*** that can provide an environment for the testing of those

practices that can be modified based on feedback and results from live trials. Regulation (EC) No 178/2002 should therefore be amended accordingly.

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.

Or. en

Amendment 881
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 113

Text proposed by the Commission	*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 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 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.	(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 regulatory sandboxes***, where pathways for controlled testing, notification or authorisation are not available or appropriate ,*** 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.

Or. en

Amendment 882
Stine Bosse, Katri Kulmuni, Billy Kelleher, Sigrid Friis

Proposal for a regulation
Recital 113

Text proposed by the Commission	*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 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 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.	(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 to provide Member States with the possibility of setting up 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.

Or. en

Justification

Green & food and feed biotechnology and novel foods can help reduce agricultural land use, pesticide use, and reduce CO2 emissions.

Amendment 883
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Recital 114

Text proposed by the Commission	*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, and research and risk	***deleted***

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 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.

Or. en

Amendment 884
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 114

Text proposed by the Commission	*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, and research and risk	***deleted***

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 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.

Or. en

Amendment 885
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Recital 114

Text proposed by the Commission	*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, and research and risk assessment bodies, regulatory sandboxes	(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 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.

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 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. ***Such delivery arrangements should fully respect good distribution practice in order to ensure that investigational and auxiliary medicinal products are appropriately stored, transported and supplied before they reach the subject. This is essential not only for subject safety, but also for the reliability of clinical trial results, as inefficacy, adverse events or other outcomes should be attributable to the medicinal product under investigation and not to inappropriate delivery, transport or storage conditions.Delivery through a community or hospital pharmacy should therefore be preferred where appropriate, as pharmacies are equipped to ensure proper storage and controlled supply of medicines and to provide subjects with advice on their appropriate use. The appropriate use, storage and delivery of medicines are integral to the quality and interpretability***

of clinical trial results. The delivery of investigational or auxiliary medicinal products should be organised without prejudice to Member States' competence for the organisation and delivery of health services and medical care and to national rules governing pharmacy practice, dispensing, supply, administration and the role of healthcare professionals and persons authorised to supply medicinal products.

Or. en

Amendment 886
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sigrid Friis

Proposal for a regulation
Recital 114

Text proposed by the Commission	*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, 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 and function in such a way as to enable the collection of sound and useful information to inform future regulatory changes, rules	(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***. Regulatory sandboxes should primarily aim to support innovation and the generation of robust and useful evidence, which is essential for accelerating the development and uptake of innovative solutions and enabling the food chain to respond effectively to present and future challenges, while ensuring a high level of protection of human and animal health and the environment. When designing and operating regulatory sandboxes, Member States should be allowed to take into account national sensitivities, including those reflected in their***

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.

contributions to institutional discussions at Union level, in line with the principles of proportionality and subsidiarity. 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 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.

Or. en

Amendment 887
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 114

Text proposed by the Commission	*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, 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	(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,

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 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.

and consumer behaviours***. Such regulatory sandboxes should be designed to generate evidence and regulatory insight that can inform the Union level, including structured reporting and knowledge-sharing, so that the results can inform guidance, implementation, and where appropriate, future adjustments to Union rules***. 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 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.

Or. en

Amendment 888
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 114

Text proposed by the Commission	*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	(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 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.	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 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. ***The regulatory sandboxes should not affect the supervisory and corrective powers of the competent authorities and the liability of the participants, authorisation holders, applicants for authorisations, or any entities involved in the lifecycle of the product.***

Or. en

Amendment 889
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 114

Text proposed by the Commission	*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, 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 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.	(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 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. ***The regulatory sandbox should not affect the supervisory and corrective powers of the competent authorities and the liability of the participants, authorisation holders, applicants for authorisations, or any entities involved in the lifecycle of the product.***

Or. en

Amendment 890
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation

Recital 114 a (new)

Text proposed by the Commission	*Amendment*
	(114a) The Commission should be empowered to establish a regulatory sandbox, based on the recommendation of the Authority, when the development and authorisation of an novel or innovative food product cannot be achieved under the requirements applicable, due to methods related to products or their inherent scientific or technical characteristics. A regulatory sandbox facilitates the development, validation and testing of the innovative element of the products under the supervision of the Authority and competent authorities while allowing, where necessary and justified, the adaption of the regulatory requirements for those products. However, such adaptations should not lower applicable safety, authorisation, labelling, traceability, consumer information or risk assessment requirements.

Or. en

Amendment 891
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sigrid Friis, Sophie Wilmès

Proposal for a regulation
Recital 114 a (new)

Text proposed by the Commission	*Amendment*
	(114a) Regulatory sandboxes should function not only as testing environments, but also as structured learning environments where experience from individual projects could be translated into regulation, approval pathways and guidance which supports the development and bringing to market of future biotechnology solutions. Biotechnology can be widely relevant across sectors such

as agriculture, environment, food and feed, industry and energy. Therefore, coordination and joint learning between relevant competent authorities, in particular where biotechnology solutions interact with several regulatory frameworks or fall between established regulatory categories, should also be elements of the regulatory sandboxes.

Or. en

Amendment 892
Margarita de la Pisa Carrión, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Recital 114 a (new)

Text proposed by the Commission	*Amendment*
	(114a) Regulatory sandboxes should also be extended to the development of novel antimicrobial drugs and treatments, which currently face significant research and legislative complications, and which could significantly contribute to human health and Member States' response to infectious antimicrobial resistant diseases.

Or. en

Amendment 893
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Recital 114 b (new)

Text proposed by the Commission	*Amendment*
	(114b) Where practicable, biotechnology should prove its value in the context of its application. Therefore, regulatory sandboxes should, where relevant, support testing under real-life conditions

in cooperation with partners such as farmers, companies and local authorities, to asses safety, environmental, societal and other relevant conditions collectively. Particular attention should be given to facilitating the testing in existing demonstration facilities, living labs and regional innovation ecosystems, where appropriate safeguards, monitoring arrangements and risk mitigation measures are already established.

Or. en

Amendment 894
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 115

Text proposed by the Commission	*Amendment*
(115) Regulatory sandboxes should not be allowed for some products. Experience 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 Council[48] , 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	***deleted***

concerning novel plastic recycling technologies for plastics intended to come into contact with food, chapter IV of Commission Regulation (EU) 2022/1616[49] 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.

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[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).

Or. en

Amendment 895
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 115

Text proposed by the Commission	*Amendment*
(115) Regulatory sandboxes should ***not*** be allowed for ***some*** products***. Experience 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 Council[48] , 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) 2022/1616***[49]*** 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.	(115) Regulatory sandboxes should be allowed for ***food and feed biotechnology*** products***, including, under strict conditions,*** novel foods ***and innovative food production methods. Such sandboxes can support responsible innovation, competitiveness and the development of a future Union market for safe products, while enabling early*** regulatory ***learning, evidence generation and proportionate testing under strict supervision. They should not lower applicable safety standards and should ensure a high level of protection of human health, animal health, animal welfare, food and feed safety and the environment, in line with a One Health approach***. 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 ***GMO***, regulatory sandboxes should ***therefore not create parallel testing pathways where existing Union procedures already provide for controlled testing, notification or authorisation. In order to preserve legal certainty and ensure a high level of protection of human health, animal health, plant health, animal welfare and the environment, the use of regulatory sandboxes for*** products containing or consisting of ***genetically modified organisms should remain strictly limited, risk-based and*** subject to ***clear safeguards, without prejudice to*** Directive 2001/18/EC ***and other applicable Union law. It remains furthermore the competence of the national authorities to decide whether or not it should establish a regulatory sandbox in light of this provision***. 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 [49] 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.***

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[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).

Or. en

Amendment 896
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

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 should be allowed for ***innovative*** products.

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 Council[48] ***,*** 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) 2022/1616[49] 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.***

Experience has shown that certain types of novel foods trigger ethical or cultural concerns among various consumer segments regarding their acceptability. Those aspects are best addressed ***through the optional setting of sandboxes by Member States.*** The applicable rigorous regulatory framework established by Regulation (EU) 2015/2283 of the European Parliament and of the Council ***remains applicable.*** It is ***therefore*** appropriate to ***include*** novel foods ***in*** the scope of regulatory sandboxes.

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[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).

Or. en

Amendment 897
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 115

Text proposed by the Commission	*Amendment*
(115) Regulatory sandboxes should ***not*** be allowed for ***some*** products***. Experience 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 Council[48] , 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***	(115) ***Regulatory sandboxes can provide a structured context for testing under a 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, and keeping the relevant safety, authorisation, labelling, traceability, consumer information or risk assessment requirements.*** Regulatory sandboxes should be allowed for ***food and feed biotechnology*** products***, including, under strict conditions,*** novel foods ***and innovative food production methods. Such sandboxes can support responsible innovation, competitiveness and the development of a future Union market for***

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[49] 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.

safe and sustainable products, while enabling early regulatory learning, evidence generation and proportionate testing under strict supervision. Where specific ethical or cultural concerns ***are raised in relation to a proposed sandbox activity concerning*** novel foods ***or innovative food production methods, such concerns should be duly substantiated, assessed on a case-by-case basis and taken into account where relevant under applicable Union or national law***. 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. 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[49] 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).

Or. en

Amendment 898
Stine Bosse, Katri Kulmuni, Billy Kelleher, Sigrid Friis

Proposal for a regulation
Recital 115

Text proposed by the Commission	*Amendment*
(115) Regulatory sandboxes should ***not be allowed for some products. Experience 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 Council[48] , 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) 2022/1616[49] already establishes a framework that is meant to encourage the development of such novel technologies without prior authorisation. To ensure uniform rules on	(115) ***Regulatory sandboxes shall provide a structured context for testing innovative products under a controlled framework and support responsible innovation, regulatory learning, evidence generation and proportionate testing under strict supervision while ensuring a high level of protection of human health, animal health, animal welfare, food and feed safety, consumer protection and the environment. Where a proposed regulatory sandbox concerns novel foods or innovative food production methods, any ethical, cultural or consumer concerns should be duly substantiated in a transparent and proportionate manner. The assessment of such concerns should not prejudice the primacy of science-based risk assessment and evidence-based decision-making. Such*** regulatory sandboxes should ***facilitate the generation of evidence and regulatory learning, ultimately contributing to boosting*** consumer ***confidence, and should not lower*** applicable ***safety, authorisation, labelling, traceability, consumer information or risk assessment requirements***.

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.

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[49] 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

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[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).	[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).

Or. en

Justification

The Commission's exclusion of novel foods from regulatory sandboxes on the grounds of cultural sensitivity is insufficiently substantiated. The rationale provided is not supported by scientific evidence, nor does take into account the significant social, economic, and innovation-related consequences of such an exclusion for both society and the European food industry.

Europe's novel foods ecosystem is driven primarily by innovators, start-ups, and SMEs. At a time when the EU is seeking to strengthen food security and reduce its dependence on non-EU countries, excluding novel foods from regulatory sandboxes sends a contradictory signal. Diversifying food value chains and increasing their resilience to geopolitical shocks requires regulatory frameworks that enable, rather than constrain, responsible innovation.

Concerns regarding novel foods have been raised by a small number of Member States and typically relate to specific product categories rather than the novel foods sector as a whole. Treating novel foods as a homogeneous category and excluding them wholesale from regulatory sandboxes disregards their diversity, which ranges from seeds and fungi to a wide variety of other food sources.

Regulatory sandboxes are precisely the tool needed to address uncertainty and public concerns in a transparent and evidence-driven manner. They would allow authorities, innovators, and consumers to generate real-world data on safety, sustainability, and consumer perception while operating under strict regulatory oversight and maintaining the EU's high food safety standards. Excluding novel foods from this mechanism not only limits evidence generation but also delays consumer awareness and acceptance and informed public debate. In addition, it could jeopardise the EU's leading position in food research and innovation and biotechnology.

Amendment 899
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 115

Text proposed by the Commission	*Amendment*

(115) ***Regulatory sandboxes should not be allowed for some products. Experience 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 Council[48] , 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) 2022/1616[49] 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.

(115) 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[49] 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.

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[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).

[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).

Or. en

Amendment 900
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 115

Text proposed by the Commission	*Amendment*
(115) Regulatory sandboxes should not ***be allowed for some products. Experience 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 Council[48] , 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	(115) Regulatory ***sandboxes can provide a structured context for testing under a 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. 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*** sandboxes should not ***lower*** applicable ***safety, authorisation, labelling, traceability, consumer information or risk assessment***

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[49] 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.

requirements. 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[49] 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.

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[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:

[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).

http://data.europa.eu/eli/reg/2022/1616/oj).

Or. en

Amendment 901
Jessica Polfjärd

Proposal for a regulation
Recital 115

Text proposed by the Commission	*Amendment*
(115) Regulatory sandboxes should not be allowed for some products***. Experience 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 Council[48] , 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) 2022/1616[49] 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	(115) Regulatory sandboxes should not be allowed for some products. 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[49] 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.

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).

[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).

Or. en

Amendment 902
Aura Salla

Proposal for a regulation
Recital 115

Text proposed by the Commission	*Amendment*
(115) Regulatory sandboxes should ***not*** be allowed for ***some*** products. ***Experience 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 Council[48] , it is appropriate to ***exclude***	(115) Regulatory sandboxes should be allowed for ***innovative biotechnology*** products. The applicable rigorous regulatory framework established by Regulation (EU) 2015/2283 of the European Parliament and of the Council[48]***remains applicable. Therefore***, it is appropriate to ***include*** novel foods ***in*** the scope of regulatory sandboxes. For GMOs legal pathways exist to allow testing of innovations, such as under Part B of

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) 2022/1616[49] 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.

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[49] 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.

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[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:

[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). http://data.europa.eu/eli/reg/2022/1616/oj).

Or. en

Justification

Regulatory sandboxes should also be available for novel foods, where appropriate safeguards are ensured.

Amendment 903
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Recital 115

Text proposed by the Commission	*Amendment*
(115) Regulatory sandboxes should not be allowed for some products. Experience 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 ***Council[48] , 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) 2022/1616[49] already establishes a framework that is meant to encourage the development of such novel technologies without prior	(115) Regulatory sandboxes should not be allowed for some products. Experience 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 ***Council[48] which ensures a high level of consumer protection, this Regulation should not create alternative pathways for their development, assessment or placing on the market***. 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[49]

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.

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 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.

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[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).

Or. en

Amendment 904
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 115 a (new)

Text proposed by the Commission	*Amendment*
	(115a) The development of novel foods and other food innovations offers considerable promise for addressing

disease, particularly in the context of metabolic disorders, where targeted nutritional support can improve recovery, limit complications and strengthen overall patient care. Bioactive compounds derived from such foods play a recognised role in the management of chronic illness and form a critical part of treatment pathways for rare congenital conditions. At the same time, the emergence of innovative food production methods is giving rise to a distinct industrial sector closely tied to biotechnology, biomanufacturing and research-driven innovation. Given these dual dimensions, the Union needs to ensure that progress in biotechnology translates into tangible health and public health benefits, including faster access for patients and healthcare systems to products that have undergone rigorous scientific validation, without compromising consumer protection or safety standards. The Union equally needs to safeguard its position relative to global competitors in this field, given its strategic relevance to industrial competitiveness, investment flows, scale-up capacity .

Or. en

Amendment 905
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 115 a (new)

Text proposed by the Commission	*Amendment*
	(115a) Innovative food technologies, including novel foods and advanced fermentation, have the potential to contribute to more sustainable, resilient and diversified food systems in the Union. By enabling the production of high-quality food ingredients with controlled processes, such technologies can support food safety, food security and improved

nutritional outcomes. At the same time, they may contribute to reducing environmental pressures, including greenhouse gas emissions, land and water use, and to lowering the risk of zoonotic diseases and antimicrobial resistance, in line with a One Health approach. Strengthening the Union's capacity in these emerging technologies is essential to reinforce its strategic autonomy, ensure long-term resilience and competitiveness, and secure a strong position in global value chains, and the Union should not unduly constrain its ability to develop and deploy such innovations in an emerging global market.

Or. en

Amendment 906
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 115 a (new)

Text proposed by the Commission	*Amendment*
	(115a) Innovative food technologies, including novel foods, precision fermentation 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. 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.

Or. en

Amendment 907
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 115 a (new)

Text proposed by the Commission	*Amendment*
	(115a) Innovative food technologies, including novel foods, precision fermentation 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. 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.

Or. en

Amendment 908
Christine Anderson

Proposal for a regulation
Recital 115 a (new)

Text proposed by the Commission	*Amendment*
	(115a) Certain health biotechnology

products and interventions may raise regulatory questions because their development, assessment or use depends on adaptive product composition, pathogen-susceptibility guided selection, specific conditions of administration, structured therapeutic support, patient monitoring, long-term follow-up, patient-reported or functional outcomes, real-world evidence or the interaction of pharmacological and non-pharmacological elements. Union rules should be capable of accommodating such models where this is scientifically justified and where patient safety, informed consent, ethical review, traceability, quality control, data protection and scientific validity are fully ensured.

Or. en

Amendment 909
Peter Liese

Proposal for a regulation
Recital 115 a (new)

Text proposed by the Commission	*Amendment*
	(115a) This Regulation shall fully respect Union law on the ethical limits of biotechnology, in particular Directive 98/44/EC, Article 6, which excludes from patentability the use of human embryos for industrial or commercial purposes and processes for reproductive cloning or germ-line modification.

Or. en

Justification

The Act must respect the Union's long-standing ban on patentability of inventions that involve creating human embryos, reproductive cloning or germ-line modification. This avoids any implication that the new biotech framework could weaken existing ethical red lines.

Amendment 910
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 116

Text proposed by the Commission	*Amendment*
(116) To ensure uniform conditions and principles for the setting up, operation and supervision of Regulatory sandboxes, implementing powers should be conferred on the Commission in the context of Regulation (EC) No 178/2002. Those implementing powers should be exercised in accordance with Regulation (EU) 182/2011 of the European Parliament and of the Council[50] . In case of emergencies, the Commission may provisionally adopt an measures in accordance with an urgency procedure requesting the suspension of the regulatory sandbox concerned.	***deleted***
[50] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).	

Or. en

Amendment 911
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 117

Text proposed by the Commission	*Amendment*
(117) Considering the additional financial burden established on the Authority with	(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***.	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 ***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, scale-ups or research-driven undertakings, while continuing to fully safeguard the Authority's independence and scientific integrity.***

Or. en

Justification

According to EFSA's founding regulation, the authority carries out its risk assessments by relying on voluntary experts from Member States (MS) including universities, research institutes, and risk authorities. This makes EFSA' work vulnerable and dependent on MS availabilities.

The extension of the EFSA's mandate under this proposal for Regulation entails additional scientific, technical, and administrative tasks. To ensure that EFSA can continue to deliver high-quality, independent, and timely scientific advice, it is essential that its resources evolve in line with its responsibilities.

Introducing a fee-based contribution for specific EFSA services provided at the request, or for specific services would support the sustainable financing of these new tasks. Such an approach is consistent with existing Union practice for decentralised agencies such as EMA and ECHA and allows EFSA to allocate sufficient expertise and capacity without compromising its independence or scientific integrity.

Importantly, the introduction of fees does not undermine the Authority's independence or scientific integrity, provided that fees are set in a transparent, proportionate, and cost-related manner, and that appropriate governance and oversight safeguards are in place.

Amendment 912
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 117

Text proposed by the Commission	*Amendment*
(117) Considering the additional financial	(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.	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***, within limits that are manageable for all operators***.

Or. ro

Amendment 913
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

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 could be considered***.	(117) Considering the additional financial burden established on the Authority with the expansion of its mandate following the amendments set out in this Regulation, ***additional resources should be ensured through stable and sustainable public funding under the Union budget***.

Or. en

Justification

EFSA must have stable public funding to deliver independent, science-based risk assessments. Financing the Authority through industry fees would create financial uncertainty and undermine its independence. Adequate public funding is therefore essential to maintain consumer trust and a high level of food safety.

Amendment 914
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 117 a (new)

Text proposed by the Commission	*Amendment*
	(117a) Notes that EFSA's scientific opinions are adopted collectively by

EFSA's panels, which comprise independent experts and ensure that conclusions are reached through a robust, transparent, and collegial decision-making process rather than by individual staff members, whereas the expert staff category works under EFSA's policy of independence.

Or. en

Amendment 915
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Recital 118

Text proposed by the Commission	*Amendment*
(118) Clinical trials with advanced investigational therapy medicinal products (ATMPs), including those consisting or containing genetically modified organisms (GMOs) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council[51] , can provide early access to transformative treatments for patients with rare or otherwise untreatable conditions and are important to prepare for the marketing authorisation of the medicinal products for such treatments. The nature and design of certain advanced investigational therapy medicinal products is such that the risks to human health and the environment resulting from a deliberate release of a GMO into the environment are, in practice, either excluded or negligible. For example, in viral vectors, which are genetically modified viruses used to deliver genetic material into cells, the wild-type virus genome is largely removed resulting in replication-defective recombined particles. As these particles cannot reproduce themselves, they present at most a negligible risk to human health	***deleted***

and the environment.

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[51] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.4.2001, p. 1, ELI: http://data.europa.eu/eli/dir/2001/18/oj .

Or. en

Amendment 916
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 118

Text proposed by the Commission	*Amendment*
(118) Clinical trials with advanced investigational therapy medicinal products (ATMPs), including those consisting or containing genetically modified organisms (GMOs) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council[51] , can provide early access to transformative treatments for patients with rare or otherwise untreatable conditions and are important to prepare for the marketing authorisation of the medicinal products for such treatments. The nature and design of certain advanced investigational therapy medicinal products is such that the risks to human health and the environment resulting from a deliberate release of a GMO into the environment are, in practice, either excluded or negligible. For example, in viral vectors, which are genetically modified viruses used to deliver genetic material into cells, the wild-type virus genome is largely removed resulting in replication-defective recombined particles. As these particles cannot reproduce themselves, they present at most a	(118) Clinical trials with advanced investigational therapy medicinal products (ATMPs), including those consisting or containing genetically modified organisms (GMOs) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council[51] ***and the follow-on biosimilar versions of those ATMPs***, can provide early ***and broader*** access to transformative treatments for patients with rare or otherwise untreatable conditions and are important to prepare for the marketing authorisation of the medicinal products for such treatments. The nature and design of certain advanced investigational therapy medicinal products is such that the risks to human health and the environment resulting from a deliberate release of a GMO into the environment are, in practice, either excluded or negligible. For example, in viral vectors, which are genetically modified viruses used to deliver genetic material into cells, the wild-type virus genome is largely removed resulting in replication-defective recombined particles. As these particles cannot

negligible risk to human health and the environment.

reproduce themselves, they present at most a negligible risk to human health and the environment.

[51] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.4.2001, p. 1, ELI: http://data.europa.eu/eli/dir/2001/18/oj .

[51] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.4.2001, p. 1, ELI: http://data.europa.eu/eli/dir/2001/18/oj .

Or. en

Amendment 917
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 118

Text proposed by the Commission	*Amendment*
(118) Clinical trials with advanced investigational therapy medicinal products (ATMPs), including those consisting or containing genetically modified organisms (GMOs) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the ***Council[51] ,*** can provide early access to transformative treatments for patients with rare or otherwise untreatable conditions and are important to prepare for the marketing authorisation of the medicinal products for such treatments. The nature and design of certain advanced investigational therapy medicinal products is such that the risks to human health and the environment resulting from a deliberate release of a GMO into the environment are, in practice, either excluded or negligible. For example, in viral vectors, which are genetically modified viruses used to deliver genetic material into cells, the wild-type virus genome is largely removed resulting in replication-defective recombined particles.	(118) Clinical trials with advanced investigational therapy medicinal products (ATMPs), including those consisting or containing genetically modified organisms (GMOs) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the ***Council51 , and the follow-on biosimilar versions of those ATMPs*** can provide early ***and broader*** access to transformative treatments for patients with rare or otherwise untreatable conditions and are important to prepare for the marketing authorisation of the medicinal products for such treatments. The nature and design of certain advanced investigational therapy medicinal products is such that the risks to human health and the environment resulting from a deliberate release of a GMO into the environment are, in practice, either excluded or negligible. For example, in viral vectors, which are genetically modified viruses used to deliver genetic material into cells, the wild-type virus genome is largely removed resulting

As these particles cannot reproduce themselves, they present at most a negligible risk to human health and the environment.

in replication-defective recombined particles. As these particles cannot reproduce themselves, they present at most a negligible risk to human health and the environment.

[51] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.4.2001, p. 1, ELI: http://data.europa.eu/eli/dir/2001/18/oj .

Or. en

Justification

With the first CGT products approaching loss of exclusivity (e.g. Yescarta EPAR and Spinraza EPAR), Europe faces an immense opportunity to become an ATMP excellence centre both industrially (capability and capacity), while also enabling broader access for all patients that need those life-changing therapies, including during biosimilar ATMP development process.

Amendment 918
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 118

Text proposed by the Commission

(118) Clinical trials with advanced investigational therapy medicinal products (ATMPs), including those consisting or containing genetically modified organisms (GMOs) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council[51] , can provide early access to transformative treatments for patients with rare or otherwise untreatable conditions and are important to prepare for the marketing authorisation of the medicinal products for such treatments. The nature and design of certain advanced investigational therapy

Amendment

(118) Clinical trials with advanced investigational therapy medicinal products (ATMPs) ***and vaccines***, including those consisting or containing genetically modified organisms (GMOs) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council [51] , can provide early access to transformative ***and curative*** treatments for patients with rare or otherwise untreatable conditions and are important to prepare for the marketing authorisation of the medicinal products for such treatments. The nature and design of

medicinal products is such that the risks to human health and the environment resulting from a deliberate release of a GMO into the environment are, in practice, either excluded or negligible. For example, in viral vectors, which are genetically modified viruses used to deliver genetic material into cells, the wild-type virus genome is largely removed resulting in replication-defective recombined particles. As these particles cannot reproduce themselves, they present at most a negligible risk to human health and the environment.	certain advanced investigational therapy medicinal products ***or vaccines*** is such that the risks to human health and the environment resulting from a deliberate release of a GMO into the environment are, in practice, either excluded or negligible. For example, in viral vectors, which are genetically modified viruses used to deliver genetic material into cells, the wild-type virus genome is largely removed resulting in replication-defective recombined particles. As these particles cannot reproduce themselves, they present at most a negligible risk to human health and the environment.
[51] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.4.2001, p. 1, ELI: http://data.europa.eu/eli/dir/2001/18/oj .	[51] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.4.2001, p. 1, ELI: http://data.europa.eu/eli/dir/2001/18/oj .

Or. en

Justification

The wording of Recital (118) is modified and expanded to include vaccines in line with proposed changes to Article 57(2) and 58(4).

Amendment 919
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 118

Text proposed by the Commission	*Amendment*
(118) Clinical trials with advanced investigational therapy medicinal products (ATMPs), including those consisting or containing genetically modified organisms (GMOs) within the meaning of Article 2 of Directive 2001/18/EC of the European	(118) Clinical trials with advanced investigational therapy medicinal products (ATMPs) ***and vaccines***, including those consisting or containing genetically modified organisms (GMOs) within the meaning of Article 2 of Directive

Parliament and of the Council[51] , can provide early access to transformative treatments for patients with rare or otherwise untreatable conditions and are important to prepare for the marketing authorisation of the medicinal products for such treatments. The nature and design of certain advanced investigational therapy medicinal products is such that the risks to human health and the environment resulting from a deliberate release of a GMO into the environment are, in practice, either excluded or negligible. For example, in viral vectors, which are genetically modified viruses used to deliver genetic material into cells, the wild-type virus genome is largely removed resulting in replication-defective recombined particles. As these particles cannot reproduce themselves, they present at most a negligible risk to human health and the environment.

[51] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.4.2001, p. 1, ELI: http://data.europa.eu/eli/dir/2001/18/oj .

2001/18/EC of the European Parliament and of the Council[51], can provide early access to transformative treatments for patients with rare or otherwise untreatable conditions and are important to prepare for the marketing authorisation of the medicinal products for such treatments. The nature and design of certain advanced investigational therapy medicinal products ***or vaccines*** is such that the risks to human health and the environment resulting from a deliberate release of a GMO into the environment are, in practice, either excluded or negligible. For example, in viral vectors, which are genetically modified viruses used to deliver genetic material into cells, the wild-type virus genome is largely removed resulting in replication-defective recombined particles. As these particles cannot reproduce themselves, they present at most a negligible risk to human health and the environment.

[51] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.4.2001, p. 1, ELI: http://data.europa.eu/eli/dir/2001/18/oj .

Or. en

Amendment 920
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 118 a (new)

Text proposed by the Commission	*Amendment*
	(118a) In order to ensure that health technology assessments (HTA) take into account the specific characteristics of advanced therapy medicinal products

(ATMPs), it is necessary to strengthen the methodological framework governing the use of different sources of evidence. Therefore, the Commission, in consultation with the Member State Coordination Group on Health Technology Assessment ("HTACG") and relevant stakeholders, including industry, should develop guidance on the use of real-world evidence and registry data in the health technology assessments, including cost and economic evaluation, of advanced therapy medicinal products. In parallel, the HTACG should develop dedicated methodological guidance for the performance of joint clinical assessments of advanced therapy medicinal products, taking into account the relevance and value of single-arm trials, surrogate endpoints and real-world evidence.

Or. en

Justification

Advanced therapy medicinal products frequently rely on evidence and generated outside conventional randomised controlled trials, including real-world evidence and registry data. In the absence of common guidance on how such evidence should be considered in health technology assessments, divergent approaches across Member States may create uncertainty, delay patient access and discourage innovation. Developing EU-level guidance would support greater methodological consistency, predictability and transparency in the assessment of ATMPs.

Amendment 921
András Tivadar Kulja

Proposal for a regulation
Recital 118 a (new)

Text proposed by the Commission	*Amendment*
	(118a) In order to ensure that health technology assessments appropriately reflect the specific characteristics of advanced therapy medicinal products, existing methodological guidance should take into account the use of real-world

evidence, registry data, single-arm trials and surrogate endpoints, where appropriate. The Member State Coordination Group on Health Technology Assessment should, where relevant, develop or update methodological guidance for the joint clinical assessment of advanced therapy medicinal products accordingly.

Or. en

Amendment 922
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 118 b (new)

Text proposed by the Commission	*Amendment*
	(118b) Regulation (EU) 2021/2282 recognises the importance of pooling knowledge and exchanging information between the European Medicines Agency and the HTACG on horizontal issues of scientific and technical nature relating to joint clinical assessments and joint clinical consultations. Such exchanges are particularly relevant in relation to the use of single-arm trials, surrogate endpoints and real-world evidence. To support such exchanges, and in view of its scientific and regulatory expertise, the European Medicines Agency should regularly draw up reports on its experience with the use of such sources of evidence in the assessment of medicinal products, in particular advanced therapy medicinal products. The HTACG shall take that report into account, where appropriate, when drawing up or updating methodological guidance for joint clinical assessments, in particular in relation to advanced therapy medicinal products.

Or. en

Justification

The assessment of advanced therapy medicinal products often requires consideration of evidence sources such as single-arm trials, surrogate endpoints and real-world evidence. Strengthening exchanges between the European Medicines Agency and the HTACG would help ensure that HTA methodologies benefit from existing regulatory expertise and scientific experience. An Agency report would provide a structured evidence base to support the development and updating of methodological guidance for joint clinical assessments.

Amendment 923
Anja Hazekamp, Anthony Smith, Sebastian Everding

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 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	***deleted***

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.

Or. en

Amendment 924
Kristoffer Storm

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 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	(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 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 ***states*** 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***.	(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.

Or. en

Amendment 925
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

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 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	(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 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 ***or vaccines*** from the requirement to submit an environmental risk assessment, sponsors of clinical trials should, however, submit a ***reasoned justification*** as part of the clinical trial application that explains why the advanced investigational therapy

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.

medicinal products ***or vaccines*** 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 ***reasoned justification***. For the same considerations of a risk-proportionate approach, the above-mentioned categories of advanced investigational therapy medicinal products ***or vaccines*** 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.

Or. en

Amendment 926
Nicolás González Casares, Tiemo Wölken

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 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	(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 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.

environmental risk assessment, sponsors of clinical trials should, however, submit a declaration ***reasoned justification*** 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 ***declarationreasoned justification***. 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.

Or. en

Amendment 927
Stine Bosse, Katri Kulmuni, Billy Kelleher

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 investigational therapy medicinal products that consist or contain GMOs, which present no or negligible risks to human	(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 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.	health and the environment. Whilst it is appropriate to exempt such clearly delineated categories of advanced investigational therapy medicinal products ***or vaccines*** 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 ***or vaccines*** concerned ***fall*** 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 ***or vaccines*** 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.

Or. en

Amendment 928
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

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	(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 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.	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 ***states*** 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.

Or. en

Amendment 929
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 119 a (new)

Text proposed by the Commission	*Amendment*
	(119a) Differences in the interpretation and application of Union legislation on GMOs under Directive 2001/18/EC may

arise as regards certain non-viral delivery systems used in advanced therapy medicinal products, such as lipid nanoparticles. Investigational medicinal products employing such systems may, in particular where they are used to deliver genetic material capable of replication within the host cell or of integration into the host genome, in practice be subject to requirements equivalent to those applicable to medicinal products consisting of or containing GMOs. However, given that such systems are inherently non-propagating and are not capable of generating new delivery particles, they are not expected to pose greater risks to human health or the environment than replication-deficient viral vectors. Therefore, in order to ensure consistent application of Union law and to prevent fragmentation within the internal market, investigational medicinal products employing such non-viral delivery systems should, where they present a comparable risk profile, be treated in a manner equivalent to investigational medicinal products employing non-viable or replication-deficient viral vectors for the purpose of determining the applicability of exemptions from environmental risk assessment requirements.

Or. en

Amendment 930
Aurelijus Veryga

Proposal for a regulation
Recital 119 a (new)

Text proposed by the Commission	*Amendment*
	(119a) Advanced therapy medicinal products are increasingly developed using shared technological platforms, mechanisms of action or manufacturing approaches, while targeting distinct

molecular variants or indications. As a result, multiple investigational medicinal products may be derived from the same underlying vector, cell modification process or genetic engineering approach. In order to strengthen the Union's competitiveness in biotechnology and to facilitate the development of innovative therapies, it is appropriate to provide for proportionate, science-based regulatory approaches that enable the efficient use of prior knowledge and platform-based evidence, while ensuring a high level of protection of public health, and respect confidentiality and protection of proprietary data and designs. This is consistent with the medicines-specific and risk-proportionate approach to environmental risk assessment for medicinal products containing or consisting of genetically modified organisms established under revised Regulation […] [revised Regulation No (EC) 726/2004].

Or. en

Amendment 931
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 119 b (new)

Text proposed by the Commission	*Amendment*
	(119b) In order to ensure that the exemption from environmental risk assessment requirements for certain investigational advanced therapy medicinal products that consist or contain GMOs, which present no or negligible risks to human health and the environment, delivers effective regulatory simplification, any declaration required from the sponsor to demonstrate eligibility for such exemption should be proportionate and limited to the information strictly necessary for that

purpose. In particular, such declaration should not result in an additional administrative obligation that is equivalent, in practice, to the preparation of an environmental risk assessment.

Or. en

Amendment 932
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 119 c (new)

Text proposed by the Commission	*Amendment*
	(119c) Advanced therapy medicinal products are increasingly developed using shared technological platforms, mechanisms of action or manufacturing approaches, while targeting distinct molecular variants or indications. As a result, multiple investigational medicinal products may be derived from the same underlying vector, cell modification process or genetic engineering approach. In order to strengthen the Union's competitiveness in biotechnology and to facilitate the development of innovative therapies, it is appropriate to provide for proportionate, science-based regulatory approaches that enable the efficient use of prior knowledge and platform-based evidence, while ensuring a high level of protection of public health, and respect confidentiality and protection of proprietary data and designs. This is consistent with the medicines-specific and risk-proportionate approach to environmental risk assessment for medicinal products containing or consisting of genetically modified organisms established under revised Regulation […] [revised Regulation No (EC) 726/2004]. Where such platform technologies have been appropriately characterised and assessed, including for the purposes of determining eligibility for

exemption from environmental risk assessment, requiring sponsors to re-submit and re-justify identical information for each subsequent investigational product may lead to unnecessary duplication without increasing the level of protection for human health or the environment. The regulatory framework should therefore allow, under appropriate safeguards, reliance on previous assessments of platform technologies when determining the applicability of environmental risk assessment exemptions for investigational advanced therapy medicinal products deriving from those platform technologies.

Or. en

Amendment 933
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 120

Text proposed by the Commission	*Amendment*
(120) Scientific and technological advances are driving the development of advance therapy medicinal products (ATMPs). To future proof the ATMPs legislative framework, the power to adopt delegated acts should be delegated to the Commission to amend Regulation (EC) No 1394/2007, by clarifying the ***definition***, without extending its scope, ***of*** what constitutes a tissue engineered product, in light of technical and scientific advancements in the field of ATMPs. To that effect, the Commission should carry out appropriate consultations of the Agency and of the Substances of Human Origin Coordination Board ('the SCB').	(120) Scientific and technological advances are driving the development of advance therapy medicinal products (ATMPs). To future proof the ATMPs legislative framework, the power to adopt delegated acts should be delegated to the Commission to amend Regulation (EC) No 1394/2007, by clarifying the ***techical elements of the definitions of advanced therapy medical products***, without extending its scope, ***including but not limited to*** what constitutes a tissue engineered product, in light of technical and scientific advancements in the field of ATMPs. To that effect, the Commission should carry out appropriate consultations of the Agency and of the Substances of Human Origin Coordination Board ('the SCB').

Or. en

Amendment 934
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

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. Therefore, exemptions from environmental risk assessment requirements should 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.

Or. en

Amendment 935
Dimitris Tsiodras

Proposal for a regulation
Recital 121

Text proposed by the Commission	*Amendment*
(121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector.	(121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector

Those measures aim to foster research, development, testing, and preparing for market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and facilitate patient access across the Union. Similarly, the biotechnology development accelerators aim to provide trusted testing or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products subject to those measures are expected to be biological medicinal products ('biologicals'), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the strengthening of clinical research in Europe. This is because all biotechnology products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical research in the Union.

across the biotech value chain and life-cycle (during patent monopolies, exclusivity periods and in a multi-source competitive setting). Those measures aim to foster research, development, testing, ***manufacturing*** and preparing for market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and facilitate patient access across the Union. Similarly, the biotechnology development accelerators aim to provide trusted testing or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products subject to those measures are expected to be biological medicinal products ('biologicals'), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the strengthening of clinical research in Europe. This is because all biotechnology products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical research in the Union ***as well as on strategic partnerships, including those involving European (EEA, CH, UK) and international cooperation***.

Or. en

Justification

The Biotech Act I (health) scope should encompass the entire ecosystem: value chain, and life-cycle. Besides R&D, and services, manufacturing should be explicitly referred to.

Amendment 936
Viktória Ferenc, András Gyürk

Proposal for a regulation
Recital 121

Text proposed by the Commission	*Amendment*
(121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector. Those measures aim to foster research, development, testing, and preparing for market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and facilitate patient access across the Union. Similarly, the biotechnology development accelerators aim to provide trusted testing or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products subject to those measures are expected to be biological medicinal products ('biologicals'), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular	(121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector ***across the biotech value chain and life-cycle (during patent monopolies, exclusivity periods and in a multi-source competitive setting)***. Those measures aim to foster research, development, testing, ***manufacturing*** and preparing for market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and facilitate patient access across the Union. Similarly, the biotechnology development accelerators aim to provide trusted testing or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products subject to those measures are expected to be biological medicinal products

on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the strengthening of clinical research in Europe. This is because all biotechnology products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical research in the Union.

('biologicals'), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the strengthening of clinical research in Europe. This is because all biotechnology products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical research in the Union ***as well as on strategic partnerships, including those involving European (EEA, CH, UK) and international cooperation***.

Or. en

Amendment 937
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Recital 121

Text proposed by the Commission	*Amendment*
(121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector. Those measures aim to foster research, development, testing, and preparing for market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and	(121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector. Those measures aim to foster research, development, testing, and preparing for market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and

facilitate patient access across the Union. Similarly, the biotechnology development accelerators aim to provide trusted testing or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products subject to those measures are expected to be biological medicinal products ('biologicals'), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the strengthening of clinical research in Europe. This is because all biotechnology products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical research in the Union.	facilitate patient access across the Union***.*** ***Reducing time to market and improving predictability across development, manufacturing and uptake is also essential to strengthen the Union's attractiveness for investment in advanced therapies, particularly for SME, SMCs and biopharmaceutical mid-caps***. Similarly, the biotechnology development accelerators aim to provide trusted testing or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products subject to those measures are expected to be biological medicinal products ('biologicals'), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the strengthening of clinical research in Europe. This is because all biotechnology products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical research in the Union.

Or. en

Amendment 938
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 121

Text proposed by the Commission	*Amendment*
(121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector. Those measures aim to foster research, development, testing, and preparing for market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and facilitate patient access across the Union. Similarly, the biotechnology development accelerators aim to provide trusted testing or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products subject to those measures are expected to be biological medicinal products ('biologicals'), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the strengthening of clinical research in Europe. This is because all biotechnology products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical	(121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector. Those measures aim to foster research, development, testing, and preparing for market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and facilitate patient access across the Union***. Reducing time to market and improving predictability across development, manufacturing and uptake is also essential to strengthen the Union's attractiveness for investment in advanced therapies, particularly for SME, SMCs and biopharmaceutical mid-caps***. Similarly, the biotechnology development accelerators aim to provide trusted testing or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products subject to those measures are expected to be biological medicinal products ('biologicals'), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the strengthening of clinical research in Europe. This is because all biotechnology

research in the Union.

products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical research in the Union.

Or. en

Amendment 939
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 121

Text proposed by the Commission	*Amendment*
(121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector**.** Those measures aim to foster research, development, testing, and preparing for market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and facilitate patient access across the Union. Similarly, the biotechnology development accelerators aim to provide trusted testing or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products	(121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector ***across the biotech value chain and life-cycle (during patent monopolies, exclusivity periods and in a multi-source competitive setting)***Those measures aim to foster research, development, testing, ***manufacturing*** and preparing for market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and facilitate patient access across the Union. Similarly, the biotechnology development accelerators aim to provide trusted testing or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one

subject to those measures are expected to be biological medicinal products (‘biologicals’), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the strengthening of clinical research in Europe. This is because all biotechnology products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical research in the Union.

key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products subject to those measures are expected to be biological medicinal products (‘biologicals’), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the strengthening of clinical research in Europe. This is because all biotechnology products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical research in the Union ***as well as on strategic partnerships, including those involving European (EEA, CH, UK) cooperation***.

Or. en

Amendment 940
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 121

Text proposed by the Commission	*Amendment*
(121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector. Those measures aim to foster research, development, testing, and preparing for	(121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector ***across the biotech value chain and life-cycle (during patent monopolies,***

market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and facilitate patient access across the Union. Similarly, the biotechnology development accelerators aim to provide trusted testing or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products subject to those measures are expected to be biological medicinal products ('biologicals'), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the strengthening of clinical research in Europe. This is because all biotechnology products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical research in the Union.

exclusivity periods and in a multi-source competitive setting).. Those measures aim to foster research, development, testing, and preparing for market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and facilitate patient access across the Union. Similarly, the biotechnology development accelerators aim to provide trusted testing***, manufacturing*** or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products subject to those measures are expected to be biological medicinal products ('biologicals'), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the strengthening of clinical research in Europe. This is because all biotechnology products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical research in the Union.

Or. en

Amendment 941

Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation
Recital 121

Text proposed by the Commission	*Amendment*
(121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector. Those measures aim to foster research, development, testing, and preparing for market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and facilitate patient access across the Union. Similarly, the biotechnology development accelerators aim to provide trusted testing or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products subject to those measures are expected to be biological medicinal products ('biologicals'), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the strengthening of clinical research in Europe. This is because all biotechnology	(121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector ***across the biotech value chain and life-cycle***. Those measures aim to foster research, development, testing, ***manufacturing*** and preparing for market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and facilitate patient access across the Union. Similarly, the biotechnology development accelerators aim to provide trusted testing or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products subject to those measures are expected to be biological medicinal products ('biologicals'), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the

products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical research in the Union.

strengthening of clinical research in Europe. This is because all biotechnology products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical research in the Union.

Or. en

Amendment 942
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 122

Text proposed by the Commission	*Amendment*
(122) Amending Regulation (EU) No 536/2014 of the European Parliament and of the Council***52*** to bring simplification and shorten the time for biotechnology innovations to reach the Union market is crucial to streamline and accelerate clinical trials processes in the Union and to make the legislative framework competitive globally so as to attract more clinical research to the Union. Without an efficient, accelerated and streamlined legislative framework for clinical trials authorisation in the Union, the other measures in this Regulation, and in particular the framework for the recognition and support of ***health*** biotechnology strategic projects and high impact ***health*** biotechnology strategic projects would be deprived of their effectiveness, as ***all health biotechnology medicinal products require state*** of the ***art*** clinical research and ***a globally competitive regulatory framework for*** clinical trials ***authorisation***.	(122) Amending Regulation (EU) No 536/2014 of the European Parliament and of the ***Council [52]*** to bring simplification and shorten the time for biotechnology innovations to reach the Union market is crucial to streamline and accelerate clinical trials processes in the Union and to make the legislative framework competitive globally so as to attract more clinical research to the Union. Without an efficient, accelerated and streamlined legislative framework for clinical trials authorisation in the Union, the other measures in this Regulation, and in particular the framework for the recognition and support of ***biotechnology strategic projects, high impact*** biotechnology strategic projects and ***pan-European*** high impact biotechnology strategic projects would be deprived of their effectiveness, as ***slow, fragmented and bureaucratic clinical trial procedures delay innovation, reduce the attractiveness*** of the ***Union as a place for*** clinical research and ***postpone patient access to innovative medicinal products. The amendments to Regulation (EU) No 536/2014 should therefore make*** clinical trials ***faster, simpler, more predictable and***

more Union-coordinated, while maintaining high standards of subject safety, scientific robustness, data quality, ethical review, informed consent, protection of vulnerable subjects, data protection and good clinical practice.

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[52] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1, ELI: http://data.europa.eu/eli/reg/2014/536/oj).

Or. en

Amendment 943
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 122

Text proposed by the Commission	*Amendment*
(122) Amending Regulation (EU) No 536/2014 of the European Parliament and of the Council[52] to bring simplification and shorten the time for biotechnology innovations to reach the Union market is crucial to streamline and accelerate clinical trials processes in the Union and to make the legislative framework competitive globally so as to attract more clinical research to the Union. Without an efficient, accelerated and streamlined legislative framework for clinical trials authorisation in the Union, the other measures in this Regulation, and in particular the framework for the recognition and support of health biotechnology strategic projects and high impact health biotechnology strategic projects would be deprived of their effectiveness, as all health biotechnology medicinal products require state of the art clinical research and a	(122) Amending Regulation (EU) No 536/2014 of the European Parliament and of the Council[52] to bring simplification and shorten the time for biotechnology innovations to reach the Union market is crucial to streamline and accelerate clinical trials processes in the Union and to make the legislative framework competitive globally so as to attract more clinical research to the Union. Without an efficient, accelerated and streamlined legislative framework for clinical trials authorisation in the Union, the other measures in this Regulation, and in particular the framework for the recognition and support of health biotechnology strategic projects and high impact health biotechnology strategic projects would be deprived of their effectiveness, as all health biotechnology medicinal products require state of the art clinical research and a

globally competitive regulatory framework for clinical trials authorisation.	globally competitive regulatory framework for clinical trials authorisation. ***In this context, patient safety must remain at the core of the framework. Increased speed should indeed not come at the expense of patient safety, robust evidence, transparency, and independent, patient centric ethical review and shorter timelines must be matched with adequate resourcing of both the reporting Member State and national ethics committees to maintain high-quality.***
[52] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1, ELI: http://data.europa.eu/eli/reg/2014/536/oj).	[52] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1, ELI: http://data.europa.eu/eli/reg/2014/536/oj).

Or. en

Amendment 944
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 122

Text proposed by the Commission	*Amendment*
(122) Amending Regulation (EU) No 536/2014 of the European Parliament and of the Council[52] to bring simplification and shorten the time for biotechnology innovations to reach the Union market is crucial to streamline and accelerate clinical trials processes in the Union and to make the legislative framework competitive globally so as to attract more clinical research to the Union. Without an efficient, accelerated and streamlined legislative framework for clinical trials authorisation in the Union, the other measures in this Regulation, and in particular the framework for the recognition and support of health biotechnology strategic projects	(122) Amending Regulation (EU) No 536/2014 of the European Parliament and of the Council[52] to bring simplification and shorten the time for biotechnology innovations to reach the Union market is crucial to streamline and accelerate clinical trials processes in the Union and to make the legislative framework competitive globally so as to attract more clinical research to the Union. Without an efficient, accelerated and streamlined legislative framework for clinical trials authorisation in the Union, the other measures in this Regulation, and in particular the framework for the recognition and support of health biotechnology strategic projects

and high impact health biotechnology strategic projects would be deprived of their effectiveness, as all health biotechnology medicinal products require state of the art clinical research and a globally competitive regulatory framework for clinical trials authorisation.	and high impact health biotechnology strategic projects would be deprived of their effectiveness, as all health biotechnology medicinal products require state of the art clinical research and a globally competitive regulatory framework for clinical trials authorisation. ***In this context, patient safety must remain at the core of the framework. Increased speed should indeed not come at the expense of patient safety, robust evidence, transparency, and independent, patient centric ethical review and shorter timelines must be matched with adequate resourcing of both the reporting Member State and national ethics committees to maintain high-quality evaluations.***
[52] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1, ELI: http://data.europa.eu/eli/reg/2014/536/oj).	[52] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1, ELI: http://data.europa.eu/eli/reg/2014/536/oj).

Or. en

Justification

Need for clearer recognition within the Act that patient safety must remain at the core of the framework. In this context, shorter timelines must be accompanied by adequate resourcing of both the reporting Member State and ethics committees in order to maintain high-quality evaluations. In addition, it is important to ensure that the regulation also addresses major inequalities related to patients' rights to post-trial access to treatments, as well as barriers to cross-border clinical trials across the Union.

Amendment 945
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 122 a (new)

Text proposed by the Commission	*Amendment*
	(122a) The competitiveness of the Union as a location for clinical research depends

not only on the EU regulatory framework but also on continued investment, capacity building, and the centralisation of procedures in the clinical research ecosystems at Member State level. The Council conclusions on A Call for Action on Life Sciences for the Union's Competitiveness, approved by the Council at its 4119th meeting held on 30 September 2025, called on the Commission to improve the ecosystem for multi-country and multi-centre clinical trials, including by establishing an investment plan for clinical research. Such a plan should set out clear steps and responsibilities for establishing reliable and integrated infrastructures for carrying out clinical trials in an effective framework that utilises existing structures and expertise, to coordinate and boost multi-country and multi-centre clinical trials. Therefore, to accompany the measures amending Regulation (EU) No 536/2014, and as part of a clinical research investment plan, Member States should invest in nationally coordinated support structures, single points of contact and standardised procedures, building on models and best practices already established at national level in certain Member States, in order to help trial sponsors and Contract Research Organisations (CROs) connect with hospital departments and patients across theraupetic areas. Such streamlined services at the national level can include public-private partnerships to facilitate an expedited feasibility process, investigator identification to pinpoint the most relevant clinical researchers, trial sites, and patient recruitment potential, as well as toestablish digital trial awareness platforms and digital registries to assist patients in discovering active and open trials that are relevant for them as well as to assist sponsors in increasing study visibility. These should be encouraged in order to strengthen supportive and effective structures for launching clinical trials in Member States. Complementary

measures at European level should further be developed to increase the overall attractiveness of the EU as a priority jurisdiction to conduct clinical trials by improving coordination, reducing administrative burden, and accelerating trial set-up and conduct across Member States.

Or. en

Justification

Trial Nation is an example of a public-private partnership providing a single national entry point for life science companies, patient organisations, and clinical researchers that streamlines the clinical trial process for sponsors and trial participants -- including connecting patients and clinical practitioners directly to the relevant trials via a matching platform and aiding patients in clinical trial discovery.

Amendment 946
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 122 a (new)

Text proposed by the Commission	*Amendment*
	(122a) The Union should build on practical experience gained through coordinated initiatives such as FAST-EU, Facilitating and Accelerating Strategic Clinical Trials in the EU/EEA, to support faster, more predictable and better coordinated multinational clinical trials under the Clinical Trials Regulation. Such initiatives demonstrate that accelerated assessment can be pursued through improved coordination, parallel workflows, ethics integration and effective use of the Clinical Trials Information System, without lowering scientific, ethical or patient-safety standards. That experience should inform the implementation of this Regulation and contribute to the Union's 2030 clinical trial targets, including the objective of authorising 500 additional multinational clinical trials by the end of 2030 and

ensuring that 66% of clinical trials recruit participants within 200 days from application submission. This should be particularly relevant for strategic clinical trials addressing unmet medical need, rare diseases, paediatric conditions and advanced therapies.

Or. en

Amendment 947
Ingeborg Ter Laak

Proposal for a regulation
Recital 123

Text proposed by the Commission	*Amendment*
(123) The clinical trials offer early access to the most innovative therapies, contribute to a sustainable healthcare system, maintain scientific excellence and specialised skills and they also support prosperity in the Union. Enabling the development of innovative biological medicines through clinical trials is particularly important, since those medicines often provide life-saving therapeutic options, including in cancer care or against rare genetic conditions, and, due to their complexity, they are often more difficult and expensive to develop. Increased clinical trials in the Union for biological medicines could potentially contribute to more manufacturing in the Union, higher number and earlier regulatory submission of biological medicines for marketing authorisation applications and higher percentage of EU clinical data in marketing authorisation applications. In relation to this, biological medicines sales are key drivers of growth. In 2024, the European Union spent €228 billion on medicines at list prices, including €95 billion on biological medicines, which now comprise 41% of total pharmaceutical spending. Spending on biological medicines continues to	(123) The clinical trials offer early access to the most innovative therapies, contribute to a sustainable healthcare system, maintain scientific excellence and specialised skills and they also support prosperity in ***the Union, along with ensuring timely patient access across*** the Union. Enabling the development of innovative biological medicines through clinical trials is particularly important, since those medicines often provide life-saving therapeutic options, including in cancer care or against rare genetic conditions, and, due to their complexity, they are often more difficult and expensive to develop. Increased clinical trials in the Union for biological medicines could potentially contribute to more manufacturing in the Union, higher number and earlier regulatory submission of biological medicines for marketing authorisation applications and higher percentage of EU clinical data in marketing authorisation applications. In relation to this, biological medicines sales are key drivers of growth. In 2024, the European Union spent €228 billion on medicines at list prices, including €95 billion on biological medicines, which now comprise 41% of total pharmaceutical spending.

outpace that of small molecules (~5%) by 3x and the total prescription market, at a rate of 14.7% in the most recent period[53] . In this context, simplifying Regulation (EU) No 536/2014 and accelerating multinational clinical trials appears necessary with a view to accelerate time to market of heath biotechnology innovations and thus secure the effectiveness of the substantive provisions laid down in this Regulation.

[53] See figure 2, EU spending growth at list price levels by segment and leading therapy area, in Annex to this document.

Spending on biological medicines continues to outpace that of small molecules (~5%) by 3x and the total prescription market, at a rate of 14.7% in the most recent period[53] . In this context, simplifying Regulation (EU) No 536/2014 and accelerating multinational clinical trials appears necessary with a view to accelerate time to market of heath biotechnology innovations and thus secure the effectiveness of the substantive provisions laid down in this Regulation.

[53] See figure 2, EU spending growth at list price levels by segment and leading therapy area, in Annex to this document.

Or. en

Amendment 948
Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 123 a (new)

Text proposed by the Commission	*Amendment*
	(123a) Paediatric patients suffering from rare, life-threatening or seriously debilitating diseases often face short and clinically decisive treatment windows, during which timely identification of an eligible clinical trial can be essential. They also may exhaust the therapeutic options authorised in their Member State of residence and rely on a remaining treatment option offered exclusively through a clinical trial in another Member State. Experience in certain Member States, including the Danish Trial Nation initiative, demonstrates that recruitment into clinical trials is accelerated where the treating physician is automatically notified once a patient's electronic health record indicates eligibility against an active trial protocol. To replicate this benefit across the Union

and to address the existing asymmetry in trial access between Western and Eastern Member States, an EU-level clinical trial matching register should be established, interoperable with national electronic health record systems and aligned with the data governance framework of the European Health Data Space. Such a register should operate on the basis of explicit patient or parental/guardian consent and should be designed to notify the responsible clinician, rather than to grant automated access to patient data by third parties, so as to ensure that no paediatric patient is denied timely access to a potentially life-saving clinical trial by reason of geography or the Member State in which they are treated.

Or. en

Amendment 949
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 125 a (new)

Text proposed by the Commission	*Amendment*
	(125a) Therapeutic radiopharmaceuticals are medicinal products which, when ready for use, contain a radioactive component and are intended to treat disease. They may include radionuclide radiopharmaceuticals, where the radionuclide or its salt is the active substance, and complex radiopharmaceuticals, where the radionuclide is bound to or contained within a carrier molecule to achieve targeted accumulation. In order to support innovation, patient access and regulatory predictability in this field, it is important to ensure a coherent application of Union pharmaceutical legislation and Union radiation-protection legislation. The quality, safety, efficacy, posology and administration of

therapeutic radiopharmaceuticals should be assessed under the applicable Union pharmaceutical framework, including Directive 2001/83/EC and Regulation (EC) No 726/2004, or the corresponding revised pharmaceutical legislation, while the requirements of Council Directive 2013/59/Euratom concerning radiation protection and medical exposure should continue to apply. Such application should avoid duplicative or contradictory requirements and should take account of the specific characteristics of therapeutic radiopharmaceuticals as medicinal products.

Or. en

Amendment 950
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 125 a (new)

Text proposed by the Commission	*Amendment*
	(125a) Despite the harmonisation of the procedures for the authorisation and conduct of clinical trials under Regulation (EU) No 536/2014, significant disparities remain in access to clinical trials across the Union. Clinical trial activities continue to be concentrated in certain Member States and regions, limiting opportunities for many patients to participate in research. The Union should support measures to strengthen clinical trial capacity across all Member States and remove unnecessary barriers to the participation in clinical trials of patients living in another Member State, where no suitable clinical trial is available in their Member State of residence. To improve equitable access to clinical trials, the Commission should, in cooperation with the Member States and relevant stakeholders, develop guidance on best practices to address practical barriers to

cross-border participation.

Or. en

Justification

Patients living in Member States where no relevant clinical trial is available often face practical and financial barriers to participating in clinical trials conducted in another Member State. This is particularly the case for rare and paediatric diseases, where trial populations are small, and for highly specialised therapies that require specific expertise and infrastructure which is only available at certain sites. Improving equitable access to clinical trials will help ensure that patients across the Union can benefit from innovative therapies while strengthening the attractiveness, inclusiveness and representativeness of the European clinical research ecosystem.

Amendment 951
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 126

Text proposed by the Commission	*Amendment*
(126) The Union has unique advantages as a place for multinational clinical trials due to its large population, rich genetic diversity, scientific excellence and robust research infrastructures, and high ethical, quality and safety standards. To fully leverage these strengths and considering the key and increasing role of research and clinical trials for a thriving health biotechnology sector, it is necessary to amend the Regulation (EU) No 536/2014 to further streamline and speed up the authorisation processes especially for multinational clinical trials.	(126) The Union has unique advantages as a place for multinational clinical trials due to its large population, rich genetic diversity, scientific excellence and robust research infrastructures, and high ethical, quality and safety standards. To fully leverage these strengths and considering the key and increasing role of research and clinical trials for a thriving health biotechnology sector, it is necessary to amend the Regulation (EU) No 536/2014 to further streamline and speed up the authorisation processes especially for multinational clinical trials***, but in strict compliance with the testing periods laid down in the legislation in force in order to avoid unwanted secondary effects***.

Or. ro

Amendment 952
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 127

Text proposed by the Commission	*Amendment*
(127) To accelerate and streamline the approval processes in multinational clinical trials it is necessary to give a stronger leading role to the reporting Member State and further strengthen the principles of mutual trust and reliance. The assessment by the reporting Member State, including of the ethical aspects of the trial, should serve as a reference for the other Member States concerned. Member States concerned should complement the assessment by the reporting Member State only when necessary, and be entitled to raise considerations from ethical, relevant national law or national standard of care perspectives. Strengthening reliance on the reporting Member State's assessment would reduce duplication of work and allow Member States and sponsors to allocate resources more effectively, while ensuring high level of protection of subjects and the robustness of data.	(127) To accelerate and streamline the approval processes in multinational clinical trials it is necessary to give a stronger leading role to the reporting Member State and further strengthen the principles of mutual trust and reliance. The assessment by the reporting Member State, including of the ethical aspects of the trial, should serve as a reference for the other Member States concerned. Member States concerned should complement the assessment by the reporting Member State only when necessary, and be entitled to raise considerations from ethical, relevant national law or national standard of care perspectives. Strengthening reliance on the reporting Member State's assessment would reduce duplication of work and allow Member States and sponsors to allocate resources more effectively, while ensuring high level of protection of subjects and the robustness of data. ***Strengthening reliance on the reporting Member State's assessment would reduce duplication of work and allow Member States and sponsors to allocate resources more effectively, while ensuring high level of protection of subjects and the robustness of data.For categories of clinical trials involving products or technologies subject to additional or overlapping sectoral requirements, effective coordination between clinical trial authorities and other competent authorities may further support the efficient conduct of multinational clinical trials while maintaining high standards of subject protection and safety.***

Or. en

Justification

It is important to add that , for categories of trials subject to overlapping sectorial requirements, effective coordination between clinical trial authorities and other competent authorities is necessary, while still reducing duplication of work.

Amendment 953
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 127

Text proposed by the Commission	*Amendment*
(127) To accelerate and streamline the approval processes in multinational clinical trials it is necessary to give a stronger leading role to the reporting Member State and further strengthen the principles of mutual trust and reliance. ***The*** assessment ***by the reporting Member State, including*** of the ***ethical aspects of the trial,*** should ***serve as a reference for the other*** Member States concerned. Member States concerned should complement the assessment by the reporting Member State only when necessary, and be entitled to raise considerations from ethical, relevant national law or national standard of care perspectives. Strengthening reliance on the reporting Member State's assessment would reduce duplication of work and allow Member States and sponsors to allocate resources more effectively, while ensuring high level of protection of subjects and the robustness of data.	(127) To accelerate and streamline the approval processes in multinational clinical trials it is necessary to give a stronger leading role to the reporting Member State and further strengthen the principles of mutual trust and reliance. ***For multinational clinical trials, the scientific*** assessment ***of Part I*** of the ***application dossier and of substantial modifications*** should ***be carried out through a Clinical Trials Expert Committee, chaired and supported by the European Medicines Agency. That Committee should bring together representatives of the*** Member States concerned***, regulatory and ethics expertise and, where relevant, ERN-designated experts and patient representatives. This should reduce divergent national approaches, avoid duplicative information requests and allow Member States to raise considerations only where they are necessary for subject safety, scientific robustness, ethical review or matters of national law not harmonised by Regulation (EU) No 536/2014***. Member States concerned should complement the assessment by the reporting Member State only when necessary, and be entitled to raise considerations from ethical, relevant national law or national standard of care perspectives. Strengthening reliance on the reporting Member State's assessment would reduce duplication of work and

allow Member States and sponsors to allocate resources more effectively, while ensuring high level of protection of subjects and the robustness of data.

Or. en

Amendment 954
Tomislav Sokol

Proposal for a regulation
Recital 127 a (new)

Text proposed by the Commission	*Amendment*
	(127a) The European Health Data Space established by Regulation (EU) 2025/327 constitutes an important enabling framework for the secure cross-border use of electronic health data for clinical research and evidence generation. Synergies between this Regulation and the European Health Data Space should therefore be promoted in order to facilitate multinational clinical research and strengthen the Union's capacity to develop innovative health biotechnology.

Or. en

Amendment 955
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Recital 128

Text proposed by the Commission	*Amendment*
(128) Defined timelines in the context of clinical trials approval are necessary to guarantee speed and enhance predictability of the authorisation process, especially for multinational clinical trials. Defined maximum timelines should allow the Member State authorities with efficient	(128) Defined timelines in the context of clinical trials approval are necessary to guarantee speed and enhance predictability of the authorisation process, especially for multinational clinical trials. Defined maximum timelines should allow the Member State authorities with efficient

planning to reduce periods of inactivity and thus regulatory delays between the assessment phases and enable short procedure for clinical trial approval overall. Stronger reliance on the reporting Member State would also result in efficiency gains, improve resource allocation and would enable the shortening of the consecutive assessment steps without compromising the quality of the assessments. It would benefit the sponsors as well, as it will result in a quicker start of a clinical trial, as well as in increased transparency and predictability for more effective planning. To reduce regulatory bottlenecks by allowing coordinated interaction between Part I and Part II assessments in multinational clinical trials, their respective assessment timelines should be aligned.

planning to reduce periods of inactivity and thus regulatory delays between the assessment phases and enable short procedure for clinical trial approval overall***. In order to achieve these objectives, Member States should provide national ethics committees with sufficient resources and organisational capacity to comply with the timelines laid down in this Regulation, according to national laws***. Stronger reliance on the reporting Member State would also result in efficiency gains, improve resource allocation and would enable the shortening of the consecutive assessment steps without compromising the quality of the assessments. It would benefit the sponsors as well, as it will result in a quicker start of a clinical trial, as well as in increased transparency and predictability for more effective planning. To reduce regulatory bottlenecks by allowing coordinated interaction between Part I and Part II assessments in multinational clinical trials, their respective assessment timelines should be aligned. ***Moreover, targeted faster approval through dedicated procedural accelerated mechanisms should be provided for clinical trials concerning orphan medicinal products, considering their specific recruitment and evidence-generation challenges inherent to rare diseases.***

Or. en

Amendment 956
Margarita de la Pisa Carrión, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Recital 128

Text proposed by the Commission	*Amendment*
(128) Defined timelines in the context of clinical trials approval are necessary to guarantee speed and enhance predictability	(128) Defined timelines in the context of clinical trials approval are necessary to guarantee speed and enhance predictability

of the authorisation process, especially for multinational clinical trials. Defined maximum timelines should allow the Member State authorities with efficient planning to reduce periods of inactivity and thus regulatory delays between the assessment phases and enable short procedure for clinical trial approval overall. Stronger reliance on the reporting Member State would also result in efficiency gains, improve resource allocation and would enable the shortening of the consecutive assessment steps without compromising the quality of the assessments. It would benefit the sponsors as well, as it will result in a quicker start of a clinical trial, as well as in increased transparency and predictability for more effective planning. To reduce regulatory bottlenecks by allowing coordinated interaction between Part I and Part II assessments in multinational clinical trials, their respective assessment timelines should be aligned.	of the authorisation process, especially for multinational clinical trials. Defined maximum timelines should allow the Member State authorities with efficient planning to reduce periods of inactivity and thus regulatory delays between the assessment phases and enable short procedure for clinical trial approval overall***. Achieving these objectives also requires addressing the disparities in resourcing that persist across national ethics committees, which remain a substantial source of delay and inconsistency in part II assessment across Member States***. Stronger reliance on the reporting Member State would also result in efficiency gains, improve resource allocation and would enable the shortening of the consecutive assessment steps without compromising the quality of the assessments. It would benefit the sponsors as well, as it will result in a quicker start of a clinical trial, as well as in increased transparency and predictability for more effective planning. To reduce regulatory bottlenecks by allowing coordinated interaction between Part I and Part II assessments in multinational clinical trials, their respective assessment timelines should be aligned. ***For clinical trials concerning orphan medicinal products, targeted faster approval should be promoted through dedicated procedural accelerated mechanisms, given the particular recruitment and evidence-generation challenges inherent to rare diseases.***

Or. en

Amendment 957
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 128

Text proposed by the Commission	*Amendment*

(128) Defined timelines in the context of clinical trials approval are necessary to guarantee speed and enhance predictability of the authorisation process, especially for multinational clinical trials. Defined maximum timelines should allow the Member State authorities with efficient planning to reduce periods of inactivity and thus regulatory delays between the assessment phases and enable short procedure for clinical trial approval overall. Stronger reliance on the reporting Member State would also result in efficiency gains, improve resource allocation and would enable the shortening of the consecutive assessment steps without compromising the quality of the assessments. It would benefit the sponsors as well, as it will result in a quicker start of a clinical trial, as well as in increased transparency and predictability for more effective planning. To reduce regulatory bottlenecks by allowing coordinated interaction between Part I and Part II assessments in multinational clinical trials, their respective assessment timelines should be aligned.	(128) Defined timelines in the context of clinical trials approval are necessary to guarantee speed and enhance predictability of the authorisation process, especially for multinational clinical trials. Defined maximum timelines should allow the Member State authorities with efficient planning to reduce periods of inactivity and thus regulatory delays between the assessment phases and enable short procedure for clinical trial approval overall***. Allowing the sponsor to request interactions with the reporting Member States will streamline the communications***. Stronger reliance on the reporting Member State would also result in efficiency gains, improve resource allocation and would enable the shortening of the consecutive assessment steps without compromising the quality of the assessments. It would benefit the sponsors as well, as it will result in a quicker start of a clinical trial, as well as in increased transparency and predictability for more effective planning. To reduce regulatory bottlenecks by allowing coordinated interaction between Part I and Part II assessments in multinational clinical trials, their respective assessment timelines should be aligned.

Or. en

Amendment 958
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 128 a (new)

Text proposed by the Commission	*Amendment*
	(128a) Clinical trials conducted in third countries from highly regulated jurisdictions, where ethical and scientific standards generate data of comparable robustness and reliability to clinical trials conducted within the Union should be

considered in the light of the value they might bring. Requiring the duplication of such trials within the Union, where not justified by genuine scientific, safety or population-specific considerations, delays patient access to innovative treatments, increases development costs, particularly for small and medium-sized enterprises, start-ups and academic sponsors, and unnecessarily exposes additional trial participants to investigational interventions. Therefore, where the level of protection of trial subjects and the robustness of trial data are equivalent to those required under Union law, and where the data is relevant for a European population, the Union should facilitate the acceptance and use of clinical trial data generated in such third countries for the purposes of marketing authorisation and other regulatory procedures, including by relying on existing international scientific guidelines and mutual reliance mechanisms, without prejudice to the right of the competent authorities to request additional data where necessary to ensure the safety, efficacy and quality of the product concerned

Or. en

Amendment 959
Michalis Hadjipantela

Proposal for a regulation
Recital 128 a (new)

Text proposed by the Commission	*Amendment*
	(128a) The timely and predictable authorisation of multinational clinical trials depends not only on a strengthened role for the reporting Member State and on defined maximum timelines, but also on the operational and scientific support provided at Union level by the European Medicines Agency. By operating and

continuously improving the EU portal and the EU database, maintaining mandatory harmonised templates, facilitating coordination between the reporting Member State and the Member States concerned, and supporting adherence to the assessment timelines laid down in this Regulation, the Agency performs an essential enabling function in reducing time-to-decision for multinational clinical trials, in particular for biological medicines that rely on cross-border recruitment. The Agency should be equipped with resources and capabilities commensurate with that function.

Or. en

Amendment 960
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 128 a (new)

Text proposed by the Commission	*Amendment*
	(128a) In order to reduce administrative burden for sponsors and competent authorities, the assessment of multinational clinical trials should be organised around a single coordinated timetable, a consolidated request for information and clear limits on divergent or duplicative national requests. Sponsors should be able to rely on harmonised templates, cross-references to information already submitted through the EU portal and investigational medicinal product core dossiers. Where information remains applicable and up to date, it should not be resubmitted unless strictly necessary and duly justified for reasons of subject safety, data robustness or ethical review. This should be particularly relevant for academic sponsors, SMEs, non-profit developers and ERN-linked clinical investigators.

Or. en

Amendment 961
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Recital 128 a (new)

Text proposed by the Commission	*Amendment*
	(128a) In January 2026, the Heads of Medicines Agencies (HMA) launched the Facilitating and Accelerating Strategic Trials (FAST EU) pilot Project, offering sponsors shorter evaluation timelines for their multinational trials. Learnings from this pilot project should be reflected in the implementation of the revised clinical trial approval timelines.

Or. en

Amendment 962
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 128 b (new)

Text proposed by the Commission	*Amendment*
	(128b) Several Member States have provisions for early access to unapproved medicines: (i) Article 5(1) of Directive 2001/83/EC for individual named-patient use, and (ii) Article 83 of Regulation (EC) No 726/2004 for cohort-based compassionate use. Whereas many medicinal products are not yet approved in Europe, and where the applications may be made later, there is a need for an enhanced, more equal, and more co-ordinated approach to early access. EU-M4all procedure, based on Article 58 of Regulation (EC) 726/2004 for the European Medicines Agency, can be used

to issue a scientific opinion at the request of the World Health Organisation for products solely intended for non-European markets. Similarly, the Agency should be able to issue scientific opinions on products approved in third countries with equally stringent scientific, safety and quality standards, upon the request from Member States and other relevant actors, before having received an application for a marketing authorisation the EU, or where an application is unlikely to be submitted. Member States, healthcare systems, patient organisations and other relevant actors may have a legitimate interest in obtaining such a scientific opinion to support early access mechanisms and inform decision-making at national level and to make best use of assessments already carried out internationally.

Or. en

Amendment 963
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Recital 128 b (new)

Text proposed by the Commission	*Amendment*
	(128b) The timelines laid down in this Regulation for the authorisation of clinical trials should be understood as maximum timelines and should not operate as fixed waiting periods. Where a procedural step, assessment, review or consolidation has been completed before the expiry of the applicable timeline, the procedure should advance to the next step without undue delay, provided that the applicable scientific and ethical assessment requirements and the procedural rights of sponsors, reporting Member States and Member States concerned are fully respected. The Clinical Trials Information System should

	be adapted, where necessary, to ensure that its workflows, notifications and procedural deadlines allow the relevant authorities and sponsors to proceed to the next procedural step as soon as the relevant action has been completed. This will further reduce periods of inactivity, improve predictability for sponsors and support faster trial initiation, while maintaining robust scientific and ethical assessments.

Or. en

Amendment 964
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Recital 129

Text proposed by the Commission	*Amendment*
(129) Recognising the importance of advanced therapeutic medicinal products (ATMPs) as drivers of innovation in biotechnology and regenerative medicine, it is appropriate to introduce a series of regulatory provisions to simplify and shorten the timelines for authorisation of clinical trials in the Union. In particular, to accelerate the conduct of clinical trials investigating the ATMPs, the authorisation procedure should be shortened by removing the additional 50 days of assessment period which is currently applicable	***deleted***

Or. en

Amendment 965
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 129

Text proposed by the Commission	*Amendment*
(129) Recognising the importance of advanced therapeutic medicinal products (ATMPs) as drivers of innovation in biotechnology and regenerative medicine, it is appropriate to introduce a series of regulatory provisions to simplify and shorten the timelines for authorisation of clinical trials in the Union. In particular, to accelerate the conduct of clinical trials investigating the ATMPs, the authorisation procedure should be shortened by removing the additional 50 days of assessment period which is currently applicable	(129) Recognising the importance of advanced therapeutic medicinal products (ATMPs) ***and in anticipation of biosimilar ATMPs*** as drivers of ***health*** innovation in ***access to*** biotechnology and regenerative medicine, it is appropriate to introduce a series of regulatory provisions to simplify and shorten the timelines for authorisation of clinical trials in the Union***, as well as prepare for a multi – source ATMP environment after loss of exclusivity***. In particular, to accelerate the conduct of clinical trials investigating the ATMPs, the authorisation procedure should be shortened by removing the additional 50 days of assessment period which is currently applicable***.***

Or. en

Justification

While highly innovative today, ATMPs involve biotechnological processes and products which will eventually lose Intellectual Property and exclusivity protection to face market competition. Off-patent competition is a driver for innovation but also of further process scale-up which is contributing to industrial resilience.

The Biotech Act I (health) should be future proof and allow a full ecosystem competitiveness strategy.

Amendment 966
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 129 a (new)

Text proposed by the Commission	*Amendment*
	(129a) Member States differ significantly in the administrative and scientific resources available to their national competent authorities. Smaller Member States, and those with limited regulatory capacity, may face difficulties in assessing and maintaining marketing authorisations for the full range of

medicinal products, which can delay or deter the launch of medicines on their markets, in particular for products intended for small patient populations. Enabling a Member State to rely, on a voluntary basis, on the Agency or on another Member State for the performance of these functions, while retaining its competence over authorisation and over the organisation of its health system, would allow scarce regulatory resources to be pooled, reduce duplication, and support timely and equitable patient access to medicines across the Union.

Or. en

Amendment 967
Laurent Castillo, Aleksandar Nikolic, Valérie Deloge, Julie Rechagneux, Marie-Luce Brasier-Clain

Proposal for a regulation
Recital 130 a (new)

Text proposed by the Commission	*Amendment*
	(130a) Recalls that stringent, transparent bioethical rules that are adhered to and monitored are essential if citizens are to have confidence in these technologies; believes that each Member State should be allowed to adopt stricter rules in the field of bioethics;

Or. fr

Amendment 968
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 131 a (new)

Text proposed by the Commission	*Amendment*
	(131a) Based on current best practices,

the Member States shall include patients in ethics committees and provide them with adequate and regular training.

Or. en

Justification

Clearer recognition within the Act that patient safety must remain at the core of the framework. In this context, shorter timelines must be accompanied by adequate resourcing of both the reporting Member State and ethics committees in order to maintain high-quality evaluations. In addition, it is important to ensure that the regulation also addresses major inequalities related to patients' rights to post-trial access to treatments, as well as barriers to cross-border clinical trials across the Union.

Amendment 969
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 132 a (new)

Text proposed by the Commission	*Amendment*
	(132a) In order to strengthen patient-centred clinical research and ensure equitable access to innovative treatments across the Union, further improvements to the framework established by Regulation (EU) No 536/2014 should be considered. In particular, greater clarity should be provided regarding patients' right to post-trial access to treatments where a clinical benefit has been demonstrated, in compliance with article 34 of the Helsinki Declaration. Patient information standards and informed consent procedures should be further harmonised in collaboration with patient organisations to ensure that information provided to participants in all Member States is clear, concise, and written in language understandable to laypersons, thereby supporting genuinely informed decision-making rather than serving merely as a formal or legal requirement. Furthermore, disparities in access to clinical trials across Member States should be addressed. Clinical trials

remain concentrated in a limited number of countries and sites, leading to inequalities in patient access. Where the establishment of trial sites closer to patients' homes is not feasible, safe and coordinated cross-border access to clinical trials should be facilitated. To this end, the Commission should work in cooperation with Member States and relevant stakeholders to develop harmonised recommendations supporting such access, with a view to ensuring equal opportunities for patients across the Union to participate in clinical trials.

Or. en

Justification

Clearer recognition within the Act that patient safety must remain at the core of the framework. In this context, shorter timelines must be accompanied by adequate resourcing of both the reporting Member State and ethics committees in order to maintain high-quality evaluations. In addition, it is important to ensure that the regulation also addresses major inequalities related to patients' rights to post-trial access to treatments, as well as barriers to cross-border clinical trials across the Union

Amendment 970
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Recital 133 a (new)

Text proposed by the Commission	*Amendment*
	(133a) The introduction of a single application for combined studies will simplify the conduct of clinical trials subject to both Regulation (EU) 536/2014 and Regulation (EU) No 2017/746, contributing to a simpler interface for clinical trials that include a diagnostic test. To ensure that the proposal's objectives of simplifying such application processes are practically implemented, the provision should prevent duplications with the EUDAMED system for Clinical Investigation and Performance Studies applications. Positive outcomes and

operational learnings of the COMBINE All-In-One Pilot Study must be taken into account in implementation.

Or. en

Amendment 971
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 133 a (new)

Text proposed by the Commission	*Amendment*
	(133a) In the case of clinical trials planned to be conducted in accordance with an agreed paediatric investigation plan adopted at Union level, key elements of the development programme have already been subject to scientific assessment. In order to avoid unnecessary duplication, support timely initiation of paediatric research and make efficient use of regulatory resources, the validation and assessment of clinical trial applications for such trials should therefore be prioritised, where appropriate, while fully respecting ethical requirements and ensuring a high level of protection for paediatric participants in clinical trials.

Or. en

Justification

Clinical trials conducted in accordance with an agreed PIP have already been subject to prior scientific assessment at Union level. Clarifying this supports the prioritisation of their regulatory handling under the Clinical Trials Regulation, helps avoid unnecessary duplication, and facilitates the timely initiation of paediatric research, while preserving ethical review and child protection safeguards.

Amendment 972
Diana Iovanovici Şoşoacă

Proposal for a regulation

Recital 135

Text proposed by the Commission	*Amendment*
(135) Innovative and personalised therapies often combine the use of medicinal products with medical devices, including in vitro diagnostic medical devices. During the development of such therapies, clinical trials of one or more medicinal products may need to be combined with clinical investigation of one or more medical devices or performance studies of one or more in-vitro diagnostic medical devices. The authorisation and conduct of such combined studies are complex due to the application of requirements of two or three Union legislative frameworks in the area of health and the fact that these are typically conducted across several Member States. In order to support innovation and make efficient use of sponsors' and Member States' resources, it is necessary to put in place a dedicated pathway for the authorisation and conduct of such combined studies, involving coordinated assessment across Member States.	(135) Innovative and personalised therapies often combine the use of medicinal products with medical devices, including in vitro diagnostic medical devices. During the development of such therapies, clinical trials of one or more medicinal products may need to be combined with clinical investigation of one or more medical devices or performance studies of one or more in-vitro diagnostic medical devices. The authorisation and conduct of such combined studies are complex due to the application of requirements of two or three Union legislative frameworks in the area of health and the fact that these are typically conducted across several Member States. In order to support innovation and make efficient use of sponsors' and Member States' resources, it is necessary to put in place a dedicated pathway for the authorisation and conduct of such combined studies, involving coordinated assessment across Member States. ***Such an approach should reduce the administrative burden and avoid the duplication of assessments, while at the same time ensuring a high level of protection for trial participants and a high level of scientific quality and reliability of data generated. Coordination between the authorities responsible for medicinal products, medical devices and in-vitro diagnostic medical devices should make it easier to issue coherent decisions within a foreseeable timeframe, without prejudice to the responsibilities of these authorities under the applicable legislation. In addition, this approach should help make Europe more attractive as a place for conducting clinical trials and complex clinical studies, accelerate the development of innovative and personalised treatments and facilitate patients' access to these, while maintaining high standards of safety,***

efficiency and performance.

Or. ro

Amendment 973
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 135

Text proposed by the Commission	*Amendment*
(135) Innovative and personalised therapies often combine the use of medicinal products with medical devices, including in vitro diagnostic medical devices. During the development of such therapies, clinical trials of one or more medicinal products may need to be combined with clinical investigation of one or more medical devices or performance studies of one or more in-vitro diagnostic medical devices. The authorisation and conduct of such combined studies are complex due to the application of requirements of two or three Union legislative frameworks in the area of health and the fact that these are typically conducted across several Member States. In order to support innovation and make efficient use of sponsors' and Member States' resources, it is necessary to put in place a dedicated pathway for the authorisation and conduct of such combined studies, involving coordinated assessment across Member States.	(135) Innovative and personalised therapies often combine the use of medicinal products with medical devices, including in vitro diagnostic medical devices. During the development of such therapies, clinical trials of one or more medicinal products may need to be combined with clinical investigation of one or more medical devices or performance studies of one or more in-vitro diagnostic medical devices. The authorisation and conduct of such combined studies are complex due to the application of requirements of two or three Union legislative frameworks in the area of health and the fact that these are typically conducted across several Member States. In order to support innovation and make efficient use of sponsors' and Member States' resources, it is necessary to put in place a dedicated pathway for the authorisation and conduct of such combined studies, involving coordinated assessment across Member States ***through the Clinical Trials Expert Committee where such studies involve more than one Member State, in order to avoid inconsistent requests, duplicated reviews and unnecessary administrative delays, while preserving the safeguards required under Regulation (EU) No 536/2014, Regulation (EU) 2017/745 and Regulation (EU) 2017/746.***

Or. en

Amendment 974
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 135

Text proposed by the Commission	*Amendment*
(135) Innovative and personalised therapies often combine the use of medicinal products with medical devices, including in vitro diagnostic medical devices. During the development of such therapies, clinical trials of one or more medicinal products may need to be combined with clinical investigation of one or more medical devices or performance studies of one or more in-vitro diagnostic medical devices. The authorisation and conduct of such combined studies are complex due to the application of requirements of two or three Union legislative frameworks in the area of health and the fact that these are typically conducted across several Member States. In order to support innovation and make efficient use of sponsors' and Member States' resources, it is necessary to put in place a dedicated pathway for the authorisation and conduct of such combined studies, involving coordinated assessment across Member States.	(135) Innovative and personalised therapies often combine the use of medicinal products with medical devices, including in vitro diagnostic medical devices ***including companion diagnostics, biomarker-based testing and genomic technologies where appropriate***. During the development of such therapies, clinical trials of one or more medicinal products may need to be combined with clinical investigation of one or more medical devices or performance studies of one or more in-vitro diagnostic medical devices. The authorisation and conduct of such combined studies are complex due to the application of requirements of two or three Union legislative frameworks in the area of health and the fact that these are typically conducted across several Member States. In order to support innovation and make efficient use of sponsors' and Member States' resources, it is necessary to put in place a dedicated pathway for the authorisation and conduct of such combined studies, involving coordinated assessment across Member States.

Or. en

Amendment 975
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 135 a (new)

Text proposed by the Commission	*Amendment*
	(135a) The introduction of a single

application for combined studies will simplify the conduct of clinical trials subject to both Regulation (EU) 536/2014 and Regulation (EU) No 2017/746, contributing to a simpler interface for clinical trials that include a diagnostic, IVD or imaging test. To ensure that the proposal's objectives of simplifying such application processes is practically implemented, the provision should prevent duplications with the EUDAMED system for CI/PS applications. In this regard, the positive outcomes of the COMBINE Pilot Study must be taken into account during implementation.

Or. en

Amendment 976
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 136

Text proposed by the Commission	*Amendment*
(136) The experience gained during the Covid-19 pandemic has shown the need for the Union to swiftly take up measures to strengthen the development and access to crisis-relevant medicines, including to accelerate, simplify, and streamline the authorisation of multinational clinical trials relevant to prevent, treat or diagnose the disease caused by an emerging serious cross-border threat to health. Regulatory flexibility, including an accelerated authorisation procedure for clinical trials, is necessary to address and possibly contain an emerging health threat in a timely, efficient and coordinated manner. Therefore, it is appropriate to allow for an accelerated procedure for the authorisation of multinational clinical trials in situations where a public health emergency at Union level has been recognised in accordance with Article 23(1) of Regulation (EU) 2022/2371 of the European Parliament and	(136) The experience gained during the Covid-19 pandemic has shown the need for the Union to swiftly take up measures to strengthen the development and access to crisis-relevant medicines, including to accelerate, simplify, and streamline the authorisation of multinational clinical trials relevant to prevent, treat or diagnose the disease caused by an emerging serious cross-border threat to health. ***This need is not limited to public health emergencies. It is also particularly evident for rare diseases, where small and geographically dispersed patient populations make multinational clinical trials indispensable, and where Union-level coordination can accelerate the generation of robust clinical evidence for patients with high unmet medical needs. Around 18 to 34 million people in the Union are estimated to live with a rare disease, while no individual Member State alone can***

of the ***Council***[54] , or in situations of an emerging serious cross-border threat to health that is likely to lead to the recognition of a public health emergency at Union level. ***This should also complement measures from the*** Regulation (EU) ***2022/2372 of the Council***[55] ***on a framework of measures for ensuring the*** supply ***of crisis-relevant medical countermeasures in the event of a public health emergency at*** Union ***level***.

usually provide the scale of patients, data and expertise required for efficient clinical research in this field. The same need also arises for critical medicines and medicinal products of common interest, where clinical trials may contribute to improving availability, therapeutic alternatives, repurposing, substitution, security of supply and resilience of the Union's health systems. Regulatory flexibility, including an accelerated authorisation procedure for clinical trials, is necessary to address and possibly contain an emerging health threat in a timely, efficient and coordinated manner***.*** ***Such regulatory flexibility should also be used proactively to address structural weaknesses in the Union clinical trials environment, in particular the slower authorisation and launch of multinational clinical trials compared with other major jurisdictions, while fully maintaining patient safety, ethical standards and the scientific quality of clinical evidence***. Therefore, it is appropriate to allow for an accelerated procedure for the authorisation of multinational clinical trials in situations where a public health emergency at Union level has been recognised in accordance with Article 23(1) of Regulation (EU) 2022/2371 of the European Parliament and of the ***Council53***, or in situations of an emerging serious cross-border threat to health that is likely to lead to the recognition of a public health emergency at Union level. ***It is also appropriate to provide for such an accelerated procedure for multinational clinical trials concerning rare diseases and medicinal products falling within the scope of*** Regulation (EU) ***…/… [Critical Medicines Act], including critical medicines and medicinal products of common interest. The accelerated procedure should be designed to reduce administrative burden and duplication of requests and procedures between Member States while maintaining the high level of protection of trial participants, scientific robustness, data quality and compliance with ethical***

standards provided for in this Regulation. Such accelerated and special procedures should therefore also be available for clinical trials addressing rare or ultra-rare diseases, orphan medicinal products, paediatric conditions, advanced therapy medicinal products and medicinal products relevant for availability, security of supply***, resilience, substitution, repurposing or therapeutic alternatives for critical medicines. This should reflect the specific difficulties of conducting robust trials where patient populations are small or geographically dispersed, or where the*** Union ***has a strategic interest in accelerating evidence generation***.

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[54] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, ELI: http://data.europa.eu/eli/reg/2022/2371/oj)

[55] Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

Or. en

Amendment 977
Aurelijus Veryga

Proposal for a regulation
Recital 136

Text proposed by the Commission	*Amendment*
(136) The experience gained during the Covid-19 pandemic has shown the need for the Union to swiftly take up measures to strengthen the development and access to crisis-relevant medicines, including to	(136) The experience gained during the Covid-19 pandemic has shown the need for the Union to swiftly take up measures to strengthen the development and access to crisis-relevant medicines, including to

accelerate, simplify, and streamline the authorisation of multinational clinical trials relevant to prevent, treat or diagnose the disease caused by an emerging serious cross-border threat to health. Regulatory flexibility, including an accelerated authorisation procedure for clinical trials, is necessary to address and possibly contain an emerging health threat in a timely, efficient and coordinated manner. Therefore, it is appropriate to allow for an accelerated procedure for the authorisation of multinational clinical trials in situations where a public health emergency at Union level has been recognised in accordance with Article 23(1) of Regulation (EU) 2022/2371 of the European Parliament and of the Council[54] , or in situations of an emerging serious cross-border threat to health that is likely to lead to the recognition of a public health emergency at Union level. This should also complement measures from the Regulation (EU) 2022/2372 of the Council[55] on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

[54] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, ELI: http://data.europa.eu/eli/reg/2022/2371/oj)

[55] Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

accelerate, simplify, and streamline the authorisation of multinational clinical trials relevant to prevent, treat or diagnose the disease caused by an emerging serious cross-border threat to health. Regulatory flexibility, including an accelerated authorisation procedure for clinical trials, is necessary to address and possibly contain an emerging health threat in a timely, efficient and coordinated manner. Therefore, it is appropriate to allow for an ***centralised*** accelerated procedure ***by the EMA Emergency Task Force*** for the authorisation of multinational clinical trials in situations where a public health emergency at Union level has been recognised in accordance with Article 23(1) of Regulation (EU) 2022/2371 of the European Parliament and of the Council[54] , or in situations of an emerging serious cross-border threat to health that is likely to lead to the recognition of a public health emergency at Union level. This should also complement measures from the Regulation (EU) 2022/2372 of the Council[55] on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

[54] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, ELI: http://data.europa.eu/eli/reg/2022/2371/oj)

[55] Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

Or. en

Amendment 978

Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 136 a (new)

Text proposed by the Commission	*Amendment*
	(136a) Paediatric patients requiring access to treatments and clinical trials not available in their Member State have distinct clinical, legal and ethical needs that the general cross-border healthcare and clinical trial framework does not adequately address. They represent a developmental continuum, from neonates to adolescents, with disease-specific narrow therapeutic windows, beyond which an intervention may lose its therapeutic value or the condition may cause irreversible harm. Any cross-border movement of a sick child necessarily entails the movement of at least one parent or legal guardian, with associated costs. Therefore, there is a need for specific provisions to be established for paediatric patients within the cross-border access framework.

Or. en

Amendment 979
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 136 a (new)

Text proposed by the Commission	*Amendment*
	(136a) For rare disease clinical trials, a voluntary opt-in procedure administered by the European Medicines Agency should be available. Under that procedure, a single authorisation should be valid in all participating Member States, without requiring further national authorisation. The procedure should make use of ERN clinical expertise, ERN

registries and, where appropriate, ERN clinical trial offices, while ensuring clear allocation of sponsor or co-sponsor responsibilities, including civil liability, insurance and safety reporting. Such a procedure should support multinational clinical trials for rare, ultra-rare and complex diseases without lowering applicable standards.

Or. en

Amendment 980
Ingeborg Ter Laak

Proposal for a regulation
Recital 136 a (new)

Text proposed by the Commission	*Amendment*
	(136a) During a public health emergency or an emerging serious cross-border threat to health, the assessment capacity of Member States and the Agency may be temporarily constrained. It should therefore be possible to prioritise applications concerning medicinal products directly addressing such emergencies or threats over other applications, to the extent necessary and proportionate, while maintaining the scientific standards applicable under the relevant Union legislation.

Or. en

Amendment 981
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 136 a (new)

Text proposed by the Commission	*Amendment*
	(136a) In order to accelerate the start of clinical trials in the Union, sponsors may

request a voluntary Union-level assessment of their application by the Clinical Trials Coordination and Advisory Group (CTAG). For that purpose, a Voluntary Centralised Assessment Committee should be established within CTAG to coordinate the assessment of Parts I and II of the application dossier and to issue common assessment reports for concerned Member States.

Or. en

Amendment 982
Ingeborg Ter Laak

Proposal for a regulation
Recital 136 b (new)

Text proposed by the Commission	*Amendment*
	(136b) Delays in the authorisation of multinational clinical trials may postpone the generation of clinical evidence and consequently delay patients' access to innovative medicinal products, particularly in the context of public health emergencies, serious cross-border threats to health, rare and ultra-rare diseases and critical medicinal products. It is therefore appropriate to provide for accelerated and differentiated assessment timelines reflecting the urgency and characteristics of those categories of clinical trials. In order to improve the efficiency and consistency of the coordinated assessment, requests for supplementary information concerning Part I should be consolidated into a single request issued through the EU portal. Those measures should reduce unnecessary administrative burden, increase regulatory predictability and contribute to earlier and more equitable patient access to innovative medicinal products, while maintaining the high standards of scientific assessment, ethics and participant protection

Or. en

Amendment 983
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 136 b (new)

Text proposed by the Commission	*Amendment*
	(136b) Despite the harmonisation achieved by Regulation (EU) No 536/2014, access to clinical trials remains uneven across the Union, with trial activity concentrated in certain Member States and regions. This is particularly problematic for patients with rare diseases, rare cancers, paediatric conditions and other areas of high unmet medical need. The Union should therefore support measures to reduce practical barriers to cross-border participation in clinical trials, including through guidance on reimbursement, shared-care arrangements, information for participants and cooperation between Member States, without undermining patient safety, ethical standards or the responsibilities of sponsors and investigators.

Or. en

Amendment 984
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 136 b (new)

Text proposed by the Commission	*Amendment*
	(136b) For the voluntary opt-in special procedure clinical trials, a single integrated ethical review should be carried out by a standing Ethics Panel

within the European Medicines Agency, including ethics expertise, experts nominated by participating Member States, patient representatives with rare disease expertise and at least one ERN-designated clinical expert. That integrated ethical review should cover trial design, informed consent, risk-benefit assessment, protection of vulnerable participants and data protection, and should replace duplicative national ethics committee assessments in participating Member States, without prejudice to narrowly defined national constitutional or public-policy grounds.

Or. en

Amendment 985
Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 136 c (new)

Text proposed by the Commission	*Amendment*
	(136c) Divergent national reimbursement pathways and the uneven application of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare and of Regulation (EC) No 883/2004 on the coordination of social security systems risk delaying patient access to innovative biotechnology medicinal products and undermining the objectives of this Regulation. The Commission and the Council should therefore consider a targeted revision of that Directive and that Regulation with a view to harmonising reimbursement pathways across Member States and fostering closer cooperation between national competent authorities on reimbursement matters, so as to ensure timely and equitable access to treatment and to biotechnology medicinal products throughout the Union.

Or. en

Amendment 986
Laurence Trochu

Proposal for a regulation
Recital 137 a (new)

Text proposed by the Commission	*Amendment*
	(137a) Minors constitute a particularly vulnerable group of participants in clinical research and must be afforded the highest level of protection. Under Article 24 of the Charter of Fundamental Rights of the European Union, the best interests of children must be a primary consideration in any decision concerning them. Given the continuing scientific uncertainties as to the medium- and long-term effects of medical procedures intended to effect a medical gender transition in minors, as well as the potentially irreversible nature of some of these procedures, under the precautionary principle and the ethical requirements applicable to clinical trials laid down in Regulation (EU) No 536/2014, minors should be excluded from clinical trials involving such procedures

Or. fr

Amendment 987
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 138 a (new)

Text proposed by the Commission	*Amendment*
	(138a) Clinical trials involving authorised, well-characterised diagnostic agents or medicinal products for patient stratification or treatment monitoring, used within established clinical practice

or evidence-based protocols, where the additional procedures do not introduce more than minimal additional risk compared to normal clinical practice, may justify risk-proportionate assessment approaches.

Or. en

Justification

This amendment introduces a risk-proportionate assessment approach for clinical trials using authorised, well-characterised diagnostics or medicinal products within established clinical practice, where additional procedures pose no more than minimal additional risk, in line with the risk-based logic of Regulation (EU) No 536/2014, in order to reduce administrative burden without compromising patient safety

Amendment 988
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 139

Text proposed by the Commission	*Amendment*
(139) To ensure that clinical trials accurately represent the target population in all its diversity, and to enhance the treatments available for vulnerable populations, medicinal products which are likely to offer significant clinical benefit should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of vulnerable populations, in this context, such as incapacitated subjects, minors and pregnant or breastfeeding ***women***, requires a proper consideration of the risks of exclusion against risks of inclusion in clinical trials. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki.	(139) ***Women suffer from a historical and systematic under-representation in all stages of medical research, including in clinical trials. This gap has resulted in a lack of understanding of female anatomy, physiology, pathophysiology and broader health needs; affecting the accuracy, acceptability, efficiency and availability of medical technologies to serve women's unique health needs, including by negatively affecting investment flows.*** To ensure that clinical trials accurately represent the target population in all its diversity, and to enhance the treatments available for vulnerable populations, medicinal products which are likely to offer significant clinical benefit should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics***, including but not limited to, sex, gender, age, race, and other intersectional factors,***and the

protection of the health and well-being of subjects belonging to these groups. The protection of vulnerable populations, in this context, such as incapacitated subjects, ***and*** minors***, and the protection of key population such as*** and pregnant or breastfeeding ***individuals***, requires a proper consideration of the risks of exclusion against risks of inclusion ***in clinical trials and shall be reviewed in accordance with the upcoming publication of the EMA ICH E21 guidelines on in inclusion of pregnant and breastfeeding individuals*** in clinical trials. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki.

Or. en

Justification

Amendment drafted by the Deutsche Stiftung Weltbevölkerung (DSW)

Amendment 989
Sirpa Pietikäinen

Proposal for a regulation
Recital 139

Text proposed by the Commission	*Amendment*
(139) To ensure that clinical trials accurately represent the target population in all its diversity, and to enhance the treatments available for vulnerable populations, medicinal products which are likely to offer significant clinical benefit should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of vulnerable populations, in this context, such as incapacitated subjects, minors and pregnant or breastfeeding women, requires a proper consideration of the risks of exclusion against risks of	(139) To ensure that clinical trials accurately represent the target population in all its diversity, and to enhance the treatments available for vulnerable populations, medicinal products which are likely to offer significant clinical benefit should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics**,** and the protection of the health and well-being of subjects belonging to these groups. The protection of vulnerable populations, in this context, such as incapacitated subjects, minors and pregnant or breastfeeding women, requires a proper consideration of the risks of exclusion against risks of

inclusion in clinical trials. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki.

inclusion in clinical trials***, and shall be reviewed in accordance with the upcoming publication of the EMA ICH E21 guidelines on inclusion of pregnant and breastfeeding individuals in clinical trials***. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki.

Or. en

Amendment 990
Margarita de la Pisa Carrión, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Recital 139

Text proposed by the Commission	*Amendment*
(139) To ensure that clinical trials accurately represent the target population in all its diversity, and to enhance the treatments available for ***vulnerable*** populations, medicinal products which are likely to offer significant clinical benefit should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of ***vulnerable*** populations, in this context, such as incapacitated subjects, minors and pregnant or breastfeeding women, requires a proper consideration of the risks of exclusion against risks of inclusion in clinical trials. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki.	(139) To ensure that clinical trials accurately represent the target population in all its diversity, and to enhance the treatments available for populations ***in situations of particular vulnerability*** , medicinal products which are likely to offer significant clinical benefit should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of populations ***in situations of particular vulnerability***, in this context, such as incapacitated subjects, minors and pregnant or breastfeeding women ***and the elderly***, requires a proper consideration of the risks of exclusion against risks of inclusion in clinical trials. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki ***and Declaration of Taipei regarding research involving health data***.

Or. en

Amendment 991
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 139

Text proposed by the Commission	*Amendment*
(139) To ensure that clinical trials accurately represent the target population in all its diversity, and to enhance the treatments available for vulnerable populations, medicinal products which are likely to offer significant clinical benefit should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of vulnerable populations, in this context, such as incapacitated subjects, minors and pregnant or breastfeeding women, requires a proper consideration of the risks of exclusion against risks of inclusion in clinical trials. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki.	(139) To ensure that clinical trials accurately represent the target population in all its diversity, and to enhance the treatments available for vulnerable populations, medicinal products which are likely to offer significant clinical benefit should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of vulnerable populations, in this context, such as incapacitated subjects, minors***, elderly*** and pregnant or breastfeeding women, requires a proper consideration of the risks of exclusion against risks of inclusion in clinical trials. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki ***and Declaration of Taipei regarding research involving health data***.

Or. en

Amendment 992
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 139

Text proposed by the Commission	*Amendment*
(139) To ensure that clinical trials accurately represent the target population in all its diversity, and to enhance the treatments available for ***vulnerable*** populations, medicinal products which are	(139) To ensure that clinical trials accurately represent the target population in all its diversity, and to enhance the treatments available for populations ***in situations of particular vulnerability***,

likely to offer significant clinical benefit should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of ***vulnerable*** populations, in this context, such as incapacitated subjects, minors ***and*** pregnant or breastfeeding women, requires a proper consideration of the risks of exclusion against risks of inclusion in clinical trials. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki.

medicinal products which are likely to offer significant clinical benefit should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of populations ***in situations of particular vulnerability***, in this context, such as incapacitated subjects, minors***,*** pregnant or breastfeeding women ***and elderly***, requires a proper consideration of the risks of exclusion against risks of inclusion in clinical trials. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki.

Or. en

Amendment 993
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 139 a (new)

Text proposed by the Commission	*Amendment*
	(139a) Clinical trials conducted outside the Union play an important role in the development of medicinal products. In accordance with internationally recognised standards, including those developed within the International Council for Harmonisation, such data may be used in support of regulatory decision-making in the Union. In order to ensure a high level of protection of public health and the relevance of clinical evidence for patients in the Union, it is necessary to assess the extent to which clinical data generated outside the Union are applicable to the population of the Union pursuant to internationally harmonised principles and existing scientific methodologies, such as of the International Council for Harmonisation of Technical Requirements for

Pharmaceuticals for Human Use - ICH E5(R1): Ethnic Factors in the Acceptability of Foreign Clinical Data, hereafter referred to as ICH E5(R1) Guideline, and to medical practice within the Union. In line with ICH E5(R1) Guideline, such assessment should consider, inter alia, demographic and clinical characteristics of the study population, differences in standards of care across the world, and intrinsic and extrinsic factors that may affect the efficacy and safety of the investigational medicinal product. To ensure consistency across the lifecycle of medicinal products, relevant considerations identified during the assessment of clinical trials under Regulation (EU) No 536/2014 shall inform subsequent regulatory evaluations under the harmonised legal framework for medicinal products in the Union.

Or. en

Justification

This amendment seeks to address the increasing number of medicinal products submitted for marketing authorisation in the Union that are trialled mostly or exclusively outside the Union, thus not representing the EU population.

Amendment 994
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 139 a (new)

Text proposed by the Commission	*Amendment*
	(139a) Under this Regulation, in line with the 2026 EU Gender Equality Strategy, the entire research cycle, including clinical trials should mandate the systemic disaggregation of data by sex and gender, as well as other relevant intersectional factors such as age, to contribute to closing the data gap and building an evidence base to accurately inform the development of safe and effective health

biotechnologies.

Or. en

Justification

Amendment drafted by the Deutsche Stiftung Weltbevölkerung (DSW)

Amendment 995
Peter Liese

Proposal for a regulation
Recital 139 a (new)

Text proposed by the Commission	*Amendment*
	(139a) Clinical data intended to support Union marketing authorisation must derive from patient populations representative of the Union, as inter-ethnic biological differences can affect efficacy and safety outcomes.

Or. en

Justification

Clinical trial data generated exclusively in third countries may not always be fully representative of the Union population. As biological differences between populations can influence the efficacy and safety of medicinal products, clinical data supporting Union marketing authorisations should adequately reflect the population for which the product is intended.

Amendment 996
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 140

Text proposed by the Commission	*Amendment*
(140) Electronic health data accessed under Chapter IV of Regulation (EU) 2025/327 can offer valuable insights for clinical trials, particularly regarding the protocol or the investigational medicinal products dossier design. Therefore,	(140) Electronic health data accessed under Chapter IV of Regulation (EU) 2025/327 can offer valuable insights for clinical trials, particularly regarding the protocol or the investigational medicinal products dossier design. Therefore,

sponsors should be able to utilize this data when applying for clinical trial authorisation or modifications. Additionally, competent authorities should consider this data during the assessment of such applications.	sponsors should be able to utilize this data when applying for clinical trial authorisation or modifications***, but with appropriate rules on accessing the data in question and on access periods***. Additionally, competent authorities should consider this data during the assessment of such applications.

Or. ro

Amendment 997
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 140 a (new)

Text proposed by the Commission	*Amendment*
	(140a) The EU portal and EU database should support faster and less fragmented clinical trials by enabling the reuse of data, feasibility assessment, patient identification, recruitment, post-authorisation evidence generation and the reduction of duplicative administrative requirements. To that end, they should be cybersecure and interoperable, where appropriate, with relevant Union health data infrastructures, including the European Health Data Space, DARWIN EU, ERNs and ERN-linked registries, while fully respecting Union data protection law, health data governance rules, cybersecurity requirements, patient consent and patients' rights.

Or. en

Amendment 998
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 141 a (new)

Text proposed by the Commission	*Amendment*
	(141a) The development of a medicinal product may require various clinical trials until robust data regarding its safety and efficacy are available to support the submission of a marketing authorisation application. The knowledge of the products is built gradually during this development. Using the same dossier for an investigational medicinal product in different clinical trials helps to ensure the collection of consistent and complete information, streamlines product development, supports efficient assessment, management and oversight, and can speed up the time to the market. For this reason, a sponsor should be able to request the establishment of an investigational medicinal product core dossier and rely on this dossier by referencing it in all clinical trials related to the investigational product concerned. In order to keep the core dossier updated, sponsors should be able to request its modification. The Agency should assume the role of core dossier depositary and take responsibility for verifying completeness and suitability of the core dossier and managing the requests for its updates by requesting assessment by first Core Dossier assessing Member State. Member States concerned in the core dossier should rely on the assessment by the first Core Dossier assessing Member State. The first Core Dossier assessing Member State may consult the Member States concerned as appropriate.

Or. en

Justification

This amendment streamlines and centralises clinical trials in the Union by placing the core dossier depositary with EMA.

Amendment 999
Katri Kulmuni, Stine Bosse, Billy Kelleher, Bart Groothuis

Proposal for a regulation
Recital 142

Text proposed by the Commission	*Amendment*
(142) In the development of biosimilar medicinal products, the rapid evolution of analytical and functional characterisation methods for complex biological and biotechnological active substances calls for tailored clinical approach in biosimilar development with reduced need for confirmatory comparative clinical efficacy trials. ***Submission of a simplified investigational medicinal product dossier (IMPD) for biosimilar medicines to replace, as appropriate quality and quality control data, with a reference to the relevant additional quality substance master file or corresponding certificates would complement the shift in more risk proportionate clinical data requirements. This dual simplification and streamlining should focus on the regulatory scrutiny of key comparability data rather than require duplicative submission and assessment of the full IMPD quality dossier. Combining streamlined and robust quality data assessment with targeted clinical data generation should support an integrated and efficient development pathway for biosimilars with reduced administrative burden and development costs for biosimilar manufacturers, in particular in the Union.*** Accelerated access to biosimilar medicines to the market should support patients' access to more affordable biological therapies.	(142) In the development of biosimilar medicinal products, the rapid evolution of analytical and functional characterisation methods for complex biological and biotechnological active substances calls for tailored clinical approach in biosimilar development with reduced need for confirmatory comparative clinical efficacy trials. Accelerated access to biosimilar medicines to the market should support patients' access to more affordable biological therapies.

Or. en

Justification

Such transparency is required to support informed regulatory oversight and sound clinical decisions, while enabling properly justified, science-based development pathways before marketing authorisation.

Amendment 1000
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Recital 142

Text proposed by the Commission	*Amendment*
(142) In the development of biosimilar medicinal products, the rapid evolution of analytical and functional characterisation methods for complex biological and biotechnological active substances calls for tailored clinical approach in biosimilar development with reduced need for confirmatory comparative clinical efficacy trials. Submission of a simplified investigational medicinal product dossier (IMPD) for biosimilar medicines to replace, as appropriate quality and quality control data, with a reference to the relevant additional quality substance master file or corresponding certificates would complement the shift in more risk proportionate clinical data requirements. This dual simplification and streamlining should focus on the regulatory scrutiny of key comparability data rather than require duplicative submission and assessment of the full IMPD quality dossier. Combining streamlined and robust quality data assessment with targeted clinical data generation should support an integrated and efficient development pathway for ***biosimilars*** with reduced administrative burden and development costs for biosimilar manufacturers, in particular in the Union. Accelerated access to biosimilar medicines to the market should support patients' access to more affordable biological therapies.	(142) In the development of biosimilar medicinal products***, as well as innovative biological and biotechnological medicinal products, including orphan medicinal products, where reliance on previously assessed data is scientifically justified***, the rapid evolution of analytical and functional characterisation methods for complex biological and biotechnological active substances calls for tailored clinical approach in biosimilar development with reduced need for confirmatory comparative clinical efficacy trials. Submission of a simplified investigational medicinal product dossier (IMPD) for biosimilar medicines to replace, as appropriate quality and quality control data, with a reference to the relevant additional quality substance master file or corresponding certificates would complement the shift in more risk proportionate clinical data requirements. This dual simplification and streamlining should focus on the regulatory scrutiny of key comparability data rather than require duplicative submission and assessment of the full IMPD quality dossier. Combining streamlined and robust quality data assessment with targeted clinical data generation should support an integrated and efficient development pathway for ***such medicinal products*** with reduced administrative burden and development costs for biosimilar manufacturers, in particular in the Union. Accelerated access to biosimilar medicines to the market should support patients' access to more affordable biological therapies. ***For orphan medicinal products and other innovative biological medicines, this should help accelerate clinical development and timely patient access, while maintaining high standards of***

regulatory assessment and patient protection.

Or. en

Amendment 1001
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 142

Text proposed by the Commission	*Amendment*
(142) In the development of biosimilar medicinal products, the rapid evolution of analytical and functional characterisation methods for complex biological and biotechnological active substances calls for ***tailored*** clinical approach in biosimilar development with reduced need for confirmatory comparative clinical efficacy trials. Submission of a simplified investigational medicinal product dossier (IMPD) for biosimilar medicines to replace, as appropriate quality and quality control data, with a reference to the relevant additional quality substance master file or corresponding certificates would complement the shift in more risk proportionate clinical data requirements. This dual simplification and streamlining should focus on the regulatory scrutiny of key comparability data rather than require duplicative submission and assessment of the full IMPD quality dossier. Combining streamlined and robust quality data assessment with targeted clinical data generation should support an integrated and efficient development pathway for biosimilars with reduced administrative burden and development costs for biosimilar manufacturers, in particular in the Union. Accelerated access to biosimilar medicines to the market should support patients' access to more affordable biological therapies.	(142) In the development of biosimilar medicinal products, the rapid evolution of analytical and functional characterisation methods for complex biological and biotechnological active substances***, including next generation biosimilars such as biosimilar ATMPs,*** calls for ***revision of the biosimilar medicines application requirements, including e.g.tailored*** clinical approach in biosimilar development with reduced need for confirmatory comparative clinical efficacy trials ***acceptance of foreign-sourced global comparator (reference product) without PK bridging studies***. Submission of a simplified investigational medicinal product dossier (IMPD) for biosimilar medicines to replace, as appropriate quality and quality control data, with a reference to the relevant additional quality substance master file or corresponding certificates would complement the shift in more risk proportionate clinical data requirements. This dual simplification and streamlining should focus on the regulatory scrutiny of key comparability data rather than require duplicative submission and assessment of the full IMPD quality dossier. Combining streamlined and robust quality data assessment with targeted clinical data generation***, where scientifically justified,*** should support an integrated and efficient development pathway for biosimilars with reduced administrative burden and development costs for biosimilar

manufacturers, in particular in the Union. Accelerated access to biosimilar medicines to the market should support patients' access to more affordable biological therapies ***across a broad range of biotechnology platforms***.

Or. en

Justification

Europe's Biosimilar competitiveness advantage would benefit from fitter-for-purpose requirements for biosimilar development.

Amendment 1002
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 143

Text proposed by the Commission	*Amendment*
(143) To further optimise the use of resources for both the sponsors and Member States, the possibility to refer, in a clinical trial application, to an active substance master file or a corresponding certificate, or a certificate confirming that the quality of the substance is suitably controlled by the relevant monograph of the European Pharmacopeia, or a certified platform technology master file should be available as appropriate for any investigational medicinal product, including for ATMPs. In these cases, the simplified ***IMPD*** must contain all relevant data to the active substance or its manufacturing, which is not covered in the referenced master file or certificate.	(143) To further optimise the use of resources for both the sponsors and Member States, the possibility to refer, in a clinical trial application, to an active substance master file or a corresponding certificate, or a certificate confirming that the quality of the substance is suitably controlled by the relevant monograph of the European Pharmacopeia, or a certified platform technology master file should be available as appropriate for any investigational medicinal product, including for ATMPs ***and in line with Directive 2023/0132, which enables the use of such master files. Such references should, where appropriate, support the establishment and use of a simplified investigational medicinal product core dossier***. In these cases, the simplified ***Investigational Medicinal Product Dossier (IMPD)*** must contain all relevant data to the active substance or its manufacturing, which is not covered in the referenced master file or certificate***, without requiring resubmission of information already assessed at platform or master-file level***.

Or. en

Amendment 1003
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 143

Text proposed by the Commission	*Amendment*
(143) To further optimise the use of resources for both the sponsors and Member States, the possibility to refer, in a clinical trial application, to an active substance master file or a corresponding certificate, or a certificate confirming that the quality of the substance is suitably controlled by the relevant monograph of the European Pharmacopeia, or a certified platform technology master file should be available as appropriate for any investigational medicinal product, including for ATMPs. In these cases, the simplified IMPD must contain all relevant data to the active substance or its manufacturing, which is not covered in the referenced master file or certificate.	(143) To further optimise the use of resources for both the sponsors and Member States, the possibility to refer, in a clinical trial application, to an active substance master file or a corresponding certificate, or a certificate confirming that the quality of the substance is suitably controlled by the relevant monograph of the European Pharmacopeia, or a certified platform technology master file should be available as appropriate for any investigational medicinal product, including for ATMPs ***and in line with Directive 2023/0132, which enables the use of such master files. Such references should, where appropriate, support the establishment and use of a simplified investigational medicinal product core dossier***. In these cases, the simplified IMPD must contain all relevant data to the active substance or its manufacturing, which is not covered in the referenced master file or certificate***, without requiring resubmission of information already assessed at platform or master-file level***.

Or. en

Amendment 1004
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Recital 144

Text proposed by the Commission	*Amendment*

(144) To address the increased significance of delivery of investigational medicinal products and auxiliary medicinal products to subjects, Regulation (EU) No 536/2014 should be amended to provide a framework for the controlled transport within a Member State, where the clinical trials have been authorised, of such products directly to subjects' residences or through a dispensing pharmacy or by an authorised person, under the investigator's oversight. This ensures responsible and transparent delivery practices and adapts to the real word necessities, as demonstrated during the COVID 19 pandemic. Distribution through a dispensing ***pharmacy or by an*** authorised ***person could be considered in particular in cluster trials.***

(144) To address the increased significance of delivery of investigational medicinal products and auxiliary medicinal products to subjects, Regulation (EU) No 536/2014 should be amended to provide a framework for the controlled transport within a Member State, where the clinical trials have been authorised, of such products directly to subjects' residences or through a dispensing pharmacy or by an authorised person, under the investigator's oversight. This ensures responsible and transparent delivery practices and adapts to the real word necessities, as demonstrated during the COVID 19 pandemic. ***Such delivery arrangements should fully respect good*** distribution ***practice in order to ensure that investigational and auxiliary medicinal products are appropriately stored, transported and supplied before they reach the subject. This is essential not only for subject safety, but also for the reliability of clinical trial results, as inefficacy, adverse events or other outcomes should be attributable to the medicinal product under investigation and not to inappropriate delivery, transport or storage conditions. Delivery*** through a ***community or hospital pharmacy should therefore be preferred where appropriate, as pharmacies are equipped to ensure proper storage and controlled supply of medicines and to provide subjects with advice on their appropriate use. The appropriate use, storage and delivery of medicines are integral to the quality and interpretability of clinical trial results. The delivery of investigational or auxiliary medicinal products should be organised without prejudice to Member States' competence for the organisation and delivery of health services and medical care and to national rules governing pharmacy practice,*** dispensing***, supply, administration and the role of healthcare professionals and persons*** authorised ***to supply medicinal products.***

Or. en

Amendment 1005
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 144

Text proposed by the Commission	*Amendment*
(144) To address the increased significance of delivery of investigational medicinal products and auxiliary medicinal products to subjects, Regulation (EU) No 536/2014 should be amended to provide a framework for the controlled transport within a Member State, where the clinical trials have been authorised, of such products directly to subjects' residences or through a ***dispensing pharmacy*** or by an authorised person, under the investigator's oversight. This ensures responsible and transparent delivery practices and adapts to the ***real word*** necessities, as demonstrated during the COVID 19 pandemic. Distribution through a dispensing ***pharmacy or by an*** authorised ***person could be considered in particular in cluster trials***.	(144) To address the increased significance of delivery of investigational medicinal products and auxiliary medicinal products to subjects, Regulation (EU) No 536/2014 should be amended to provide a framework for the controlled transport within a Member State, where the clinical trials have been authorised, of such products directly to subjects' residences or through a***,*** or by an authorised person, under the investigator's oversight. This ensures responsible and transparent delivery practices and adapts to the ***real-world*** necessities, as demonstrated during the COVID-19 pandemic. ***Such delivery arrangements should fully respect good*** distribution ***practice in order to ensure that investigational and auxiliary medicinal products are appropriately stored, transported and supplied before they reach the subject. This is essential not only for subject safety, but also for the reliability of clinical trial results, as inefficacy, adverse events or other outcomes should be attributable to the medicinal product under investigation and not to inappropriate delivery, transport or storage conditions. Delivery*** through a ***community or hospital pharmacy should therefore be preferred where appropriate, as pharmacies are equipped to ensure proper storage and controlled supply of medicines and to provide subjects with advice on their appropriate use. The appropriate use, storage and delivery of medicines are integral to the quality and interpretability of clinical trial results. The delivery of***

investigational or auxiliary medicinal products should be organised without prejudice to Member States' competence for the organisation and delivery of health services and medical care and to national rules governing pharmacy practice, dispensing***, supply, administration and the role of healthcare professionals and persons*** authorised ***to supply medicinal products***.

Or. en

Justification

The amendment strengthens the link between good distribution practice, patient safety and the reliability of clinical trial results. In decentralised clinical trials, inappropriate delivery or storage before the medicine reaches the patient may affect the quality, efficacy or safety of the medicine. This could make it difficult to determine whether an observed lack of efficacy or adverse event is linked to the product itself, or to improper transport, storage or handling.Delivery through a community or hospital pharmacy should therefore be preferred where appropriate, because pharmacies have established responsibilities and infrastructure for the safe storage, controlled supply and appropriate dispensing of medicines. Pharmacists can also provide advice to subjects on correct use, storage, administration, adherence and return of the medicine, supporting both patient safety and the validity of trial outcomes.

Amendment 1006
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 144

Text proposed by the Commission	*Amendment*
(144) To address the increased significance of delivery of investigational medicinal products and auxiliary medicinal products to subjects, Regulation (EU) No 536/2014 should be amended to provide a framework for the controlled transport within a Member State, where the clinical trials have been authorised, of such products directly to subjects' residences or through a dispensing pharmacy or by an authorised person, under the investigator's oversight. This ensures responsible and transparent delivery practices and adapts to the real word necessities, as demonstrated	(144) To address the increased significance of delivery of investigational medicinal products and auxiliary medicinal products to subjects, Regulation (EU) No 536/2014 should be amended to provide a framework for the controlled transport within a Member State, where the clinical trials have been authorised, of such products directly to subjects' residences or through a dispensing pharmacy or by an authorised person, under the investigator's oversight. This ensures responsible and transparent delivery practices and adapts to the real word necessities, as demonstrated

during the COVID 19 pandemic. Distribution through a dispensing pharmacy or by an authorised person could be considered in particular in cluster trials.	during the COVID 19 pandemic. Distribution through a dispensing pharmacy or by an authorised person could be considered in particular in cluster trials. ***Such delivery arrangements should ensure compliance with good distribution practice so that investigational medicinal products and auxiliary medicinal products are appropriately stored, transported and supplied before reaching the subject. This is necessary to safeguard subject safety and the reliability of clinical trial results, ensuring that the observed efficacy and safety of the investigational medicinal product are not affected by inappropriate storage, transport or delivery conditions.***

Or. en

Amendment 1007
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 144

Text proposed by the Commission	*Amendment*
(144) To address the increased significance of delivery of investigational medicinal products and auxiliary medicinal products to subjects, Regulation (EU) No 536/2014 should be amended to provide a framework for the controlled transport within a Member State, where the clinical trials have been authorised, of such products directly to subjects' residences or through a dispensing pharmacy or by an authorised person, under the investigator's oversight. This ensures responsible and transparent delivery practices and adapts to the real word necessities, as demonstrated during the COVID 19 pandemic. Distribution through a dispensing pharmacy or by an authorised person could be considered in particular in cluster trials.	(144) To address the increased significance of delivery of investigational medicinal products and auxiliary medicinal products to subjects ***in utmost security***, Regulation (EU) No 536/2014 should be amended to provide a framework for the controlled transport within a Member State***, as well as the monitoring of this transport***, where the clinical trials have been authorised, of such products directly to subjects' residences or through a dispensing pharmacy or by an authorised person, under the investigator's oversight. This ensures responsible and transparent delivery practices and adapts to the real word necessities, as demonstrated during the COVID 19 pandemic. Distribution through a dispensing pharmacy or by an authorised person could be considered in particular in cluster trials.

Or. ro

Amendment 1008
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 144

Text proposed by the Commission	*Amendment*
(144) To address the increased significance of delivery of investigational medicinal products and auxiliary medicinal products to subjects, Regulation (EU) No 536/2014 should be amended to provide a framework for the controlled transport within a Member State, where the clinical trials have been authorised, of such products directly to subjects' residences or through a dispensing pharmacy or by an authorised person, under the investigator's oversight. This ensures responsible and transparent delivery practices and adapts to the real word necessities, as demonstrated during the COVID 19 pandemic. Distribution through a dispensing pharmacy or by an authorised person could be considered in particular in cluster trials**.**	(144) To address the increased significance of ***the safe, traceable and quality-controlled*** delivery of investigational medicinal products and auxiliary medicinal products to subjects, Regulation (EU) No 536/2014 should be amended to provide a framework for the controlled transport within a Member State, where the clinical trials have been authorised, of such products directly to subjects' residences or through a dispensing pharmacy or by an authorised person, under the investigator's oversight. This ensures responsible and transparent delivery practices and adapts to the real word necessities, as demonstrated during the COVID 19 pandemic. Distribution through a dispensing pharmacy or by an authorised person could be considered in particular in cluster trials

Or. en

Amendment 1009
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 144 a (new)

Text proposed by the Commission	*Amendment*
	(144a) Clinical trials increasingly include decentralised or hybrid elements, in particular for rare diseases and highly specialised therapies where patients may

be dispersed across several Member States. For ERN-coordinated rare disease clinical trials, direct delivery, remote monitoring and follow-up activities should therefore be possible where organised through ERN-associated investigators, dispensing pharmacies or other authorised persons, under the responsibility of the investigator and in accordance with the authorised protocol. Such arrangements should not trigger separate local site authorisations solely because delivery, monitoring or follow-up is performed remotely, provided that subject safety, traceability, data protection and pharmacovigilance safeguards are ensured.

Or. en

Amendment 1010
Oliver Schenk, Andrea Wechsler

Proposal for a regulation
Recital 146 a (new)

Text proposed by the Commission	*Amendment*
	(146a) In the specific case of radiopharmaceuticals used as diagnostic investigational medicinal products, their preparation may require specialised radiopharmaceutical expertise, dedicated infrastructure and close integration with clinical and academic research. Such preparation is often carried out in the context of publicly funded, non-commercial research, including by research organisations working in cooperation with hospitals, health centres or clinics. In order to facilitate such research while maintaining a high level of subject safety and ensuring the reliability and robustness of the data generated in the clinical trial, the exemption from the requirement to hold a manufacturing and import authorisation should also apply where such preparation is carried out in

publicly funded, non-commercial research organisations taking part in the same clinical trial in the same Member State, provided that those organisations operate on the basis of a risk-based approach under a pharmaceutical quality management system.

Or. en

Justification

Diagnostic investigational radiopharmaceuticals are frequently prepared in highly specialised academic or publicly funded non-commercial research settings which may operate in close cooperation with hospitals, health centres or clinics, but may not themselves fall within those categories. Excluding such organisations from the exemption would create unnecessary regulatory uncertainty and administrative burden for non-commercial clinical research, without providing additional benefits.

Amendment 1011
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 148

Text proposed by the Commission	*Amendment*
(148) Verification of compliance with the provisions of Regulation (EU) No 536/2014, including for verification of compliance with good clinical practices, through a system of supervision, is of fundamental importance to ensure that the objectives of this Regulation are effectively achieved. Therefore, the competent authorities of the Member States should have the power to perform on site or remote inspections, including unannounced inspections, where necessary. Where needed, the competent authority of a Member State should also be able to request support from another Member State or the Agency to carry out a joint inspection, or to request a Member State or the Agency to carry out the inspection on their behalf.	(148) Verification of compliance with the provisions of Regulation (EU) No 536/2014, including for verification of compliance with good clinical practices, through a system of supervision, is of fundamental importance to ensure that the objectives of this Regulation are effectively achieved. Therefore, the competent authorities of the Member States should have the power to perform on site or remote inspections, including unannounced inspections, where necessary***, using a group of experts with the relevant experience in the field***. Where needed, the competent authority of a Member State should also be able to request support from another Member State or the Agency to carry out a joint inspection, or to request a Member State or the Agency to carry out the inspection on their behalf.

Or. ro

Amendment 1012
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 149

Text proposed by the Commission	*Amendment*
(149) The disruptive and innovative approaches to clinical trials may require adaptations to the rules governing clinical trial approvals and conduct. To harness the benefits of this innovation while providing necessary safeguards, it is essential to create a safe space for testing new regulatory approaches and technologies. This includes, where appropriate, the use of AI in trial design, data collection, analysis, and participant interaction. For that reason, it is necessary to provide for a possibility of setting up a controlled experimental environment in the form of a regulatory sandbox, allowing regulators to test new methods for authorising and conducting clinical trials, for example, when some requirements of the dossier cannot be fully complied with, while ensuring strong safeguards for participant protection and data robustness. Insights gained from sandbox activities should inform future guidance and, where appropriate, legislative amendments.	***deleted***

Or. en

Amendment 1013
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Recital 149

Text proposed by the Commission	*Amendment*
(149) The disruptive and innovative approaches to clinical trials may require adaptations to the rules governing clinical trial approvals and conduct. To harness the benefits of this innovation while providing necessary safeguards, it is essential to create a safe space for testing new regulatory approaches and technologies. This includes, where appropriate, the use of AI in trial design, data collection, analysis, and participant interaction. ***For that reason, it is necessary to provide for a possibility of setting up a controlled experimental environment in the form of a regulatory sandbox, allowing regulators to test new methods for authorising and conducting clinical trials, for example, when some requirements of the dossier cannot be fully complied with, while ensuring strong safeguards for participant protection and data robustness. Insights gained from sandbox activities should inform future guidance and, where appropriate, legislative amendments.***	(149) The disruptive and innovative approaches to clinical trials may require adaptations to the rules governing clinical trial approvals and conduct. To harness the benefits of this innovation while providing necessary safeguards, it is essential to create a safe space for testing new regulatory approaches and technologies. This includes, where appropriate, the use of AI in trial design, data collection, analysis, and participant interaction.

Or. en

Amendment 1014
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 149

Text proposed by the Commission	*Amendment*
(149) The disruptive and innovative approaches to clinical trials may require adaptations to the rules governing clinical trial approvals and conduct. To harness the benefits of this innovation while providing necessary safeguards, it is essential to create a safe space for testing new regulatory approaches and technologies. This includes, where appropriate, the use	(149) The disruptive and innovative approaches to clinical trials may require adaptations to the rules governing clinical trial approvals and conduct. To harness the benefits of this innovation while providing necessary safeguards, it is essential to create a safe space for testing new regulatory approaches and technologies. This includes, where appropriate, the use

of AI in trial design, data collection, analysis, and participant interaction. For that reason, it is necessary to provide for a possibility of setting up a controlled experimental environment in the form of a regulatory sandbox, allowing regulators to test new methods for authorising and conducting clinical trials, for example, when some requirements of the dossier cannot be fully complied with, while ensuring strong safeguards for participant protection and data robustness. Insights gained from sandbox activities should inform future guidance and, where appropriate, legislative amendments.

of AI in trial design, data collection, analysis, and participant interaction. For that reason, it is necessary to provide for a possibility of setting up a controlled experimental environment in the form of a regulatory sandbox, allowing regulators to test new methods for authorising and conducting clinical trials, for example, when some requirements of the dossier cannot be fully complied with, while ensuring strong safeguards for participant protection and data robustness. ***Regulatory sandboxes can also benefit patients' access to groundbreaking new therapies without compromising the standards of quality, safety and efficacy.*** Insights gained from sandbox activities should inform future guidance and, where appropriate, legislative amendments. ***Regulatory sandboxes should not affect the supervisory and corrective powers of the competent authorities and the liability of the participants, such as clinical trial sponsors, marketing authorisation holders, applicants for marketing authorisation, or any entities involved in the lifecycle of the medicinal product.***

Or. en

Amendment 1015
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 149

Text proposed by the Commission	*Amendment*
(149) The disruptive and innovative approaches to clinical trials may require adaptations to the rules governing clinical trial approvals and conduct. To harness the benefits of this innovation while providing necessary safeguards, it is essential to create a safe space for testing new regulatory approaches and technologies. This includes, where appropriate, the use of AI in trial design, data collection,	(149) The disruptive and innovative approaches to clinical trials may require adaptations to the rules governing clinical trial approvals and conduct. To harness the benefits of this innovation while providing necessary safeguards, it is essential to create a safe space for testing new regulatory approaches and technologies. This includes, where appropriate, the use of AI ***and NAMs*** in trial design, data

analysis, and participant interaction. For that reason, it is necessary to provide for a possibility of setting up a controlled experimental environment in the form of a regulatory sandbox, allowing regulators to test new methods for authorising and conducting clinical trials, for example, when some requirements of the dossier cannot be fully complied with, while ensuring strong safeguards for participant protection and data robustness. Insights gained from sandbox activities should inform future guidance and, where appropriate, legislative amendments.

collection, analysis, ***decision-making*** and participant interaction. For that reason, it is necessary to provide for a possibility of setting up a controlled experimental environment in the form of a regulatory sandbox, allowing ***scientists, industry and*** regulators to test new methods for authorising and conducting clinical trials, for example, when some requirements of the dossier cannot be fully complied with, while ensuring strong safeguards for participant protection and data robustness ***and fostering mutual confidence***. ***Anonymised*** insights gained from sandbox activities should inform future guidance and, where appropriate, legislative amendments.

Or. en

Amendment 1016
Stine Bosse, Katri Kulmuni, Billy Kelleher, Martin Hojsík

Proposal for a regulation
Recital 149

Text proposed by the Commission	*Amendment*
(149) The disruptive and innovative approaches to clinical trials may require adaptations to the rules governing clinical trial approvals and conduct. To harness the benefits of this innovation while providing necessary safeguards, it is essential to create a safe space for testing new regulatory approaches and technologies. This includes, where appropriate, the use of AI in trial design, data collection, analysis, and participant interaction. For that reason, it is necessary to provide for a possibility of setting up a controlled experimental environment in the form of a regulatory sandbox, allowing regulators to test new methods for authorising and conducting clinical trials, for example, when some requirements of the dossier cannot be fully complied with, while ensuring strong safeguards for participant	(149) The disruptive and innovative approaches to clinical trials may require adaptations to the rules governing clinical trial approvals and conduct. To harness the benefits of this innovation while providing necessary safeguards, it is essential to create a safe space for testing new regulatory approaches and technologies. This includes, where appropriate, the use of AI in trial design, data collection, analysis, and participant interaction. For that reason, it is necessary to provide for a possibility of setting up a controlled experimental environment in the form of a regulatory sandbox, allowing regulators to test new methods***, including in particular human-relevant and non-animal NAMs,*** for authorising and conducting clinical trials, for example, when some requirements of the dossier cannot be fully

protection and data robustness. Insights gained from sandbox activities should inform future guidance and, where appropriate, legislative amendments.	complied with, while ensuring strong safeguards for participant protection and data robustness. Insights gained from sandbox activities should inform future guidance and, where appropriate, legislative amendments.

Or. en

Justification

Replacing "new methods" with "human-relevant and non-animal NAMs" provides greater legal clarity and scientific precision by explicitly identifying the innovative approaches covered by the provision. This amendment aligns the text with the EU's objective of promoting human-relevant, non-animal methodologies in clinical research and regulatory science.

Amendment 1017
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 149

Text proposed by the Commission	*Amendment*
(149) The disruptive and innovative approaches to clinical trials may require adaptations to the rules governing clinical trial approvals and conduct. To harness the benefits of this innovation while providing necessary safeguards, it is essential to create a safe space for testing new regulatory approaches and technologies. This includes, where appropriate, the use of AI in trial design, data collection, analysis, and participant interaction. For that reason, it is necessary to provide for a possibility of setting up a controlled experimental environment in the form of a regulatory sandbox, allowing regulators to test new methods for authorising and conducting clinical trials, for example, when some requirements of the dossier cannot be fully complied with, while ensuring strong safeguards for participant protection and data robustness. Insights gained from sandbox activities should inform future guidance and, where	(149) The disruptive and innovative approaches to clinical trials may require adaptations to the rules governing clinical trial approvals and conduct. To harness the benefits of this innovation while providing necessary safeguards, it is essential to create a safe space for testing new regulatory approaches and technologies. This includes, where appropriate, the use of AI in trial design, data collection ***and suitable protection of this data***, analysis, and participant interaction. For that reason, it is necessary to provide for a possibility of setting up a controlled experimental environment in the form of a regulatory sandbox, allowing regulators to test new methods for authorising and conducting clinical trials, for example, when some requirements of the dossier cannot be fully complied with, while ensuring strong safeguards for participant protection and data robustness. Insights gained from sandbox activities should inform future

appropriate, legislative amendments.

guidance and, where appropriate, legislative amendments.

Or. ro

Amendment 1018
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 151

Text proposed by the Commission	*Amendment*
(151) In particular, Regulation (EU) No 536/2014 should be amended torequire the processing of personal data by the sponsors and investigators where this is necessary to comply with the legal obligations imposed on them to ensure the safety and efficacy of medicinal products, when they request authorisation for and conduct clinical trials. This includes obligations to perform research activities in accordance with an authorised protocol, to perform safety reporting, and to perform archiving in accordance with Regulation (EU) No 536/2014. The relevant information to be collected according to the authorised protocol will contain personal data of the subjects, including genetic data or data concerning health. The processing of such special categories of personal data in the context of clinical trials takes place for reasons of public interest in the area of public health, in particular for ensuring high standards of medicinal products in compliance with Article 9(2), point (i), of Regulation (EU) 2016/679. Additionally, personal data may encompass identification details, such as sex and age, social insurance numbers and contact information. Moreover, sponsors may collect and process other data necessary for implementing the authorised protocol, such as the personal data of investigators. The categories of personal data to be collected and processed in the context of a specific clinical trial should be specified in the	(151) In particular, Regulation (EU) No 536/2014 should be amended torequire the processing of personal data by the sponsors and investigators where this is necessary to comply with the legal obligations imposed on them to ensure the safety and efficacy of medicinal products, when they request authorisation for and conduct clinical trials***, as well as the protection of all this data in accordance with the provisions in force***. This includes obligations to perform research activities in accordance with an authorised protocol, to perform safety reporting, and to perform archiving in accordance with Regulation (EU) No 536/2014. The relevant information to be collected according to the authorised protocol will contain personal data of the subjects, including genetic data or data concerning health. The processing of such special categories of personal data in the context of clinical trials takes place for reasons of public interest in the area of public health, in particular for ensuring high standards of medicinal products in compliance with Article 9(2), point (i), of Regulation (EU) 2016/679. Additionally, personal data may encompass identification details, such as sex and age, social insurance numbers and contact information. Moreover, sponsors may collect and process other data necessary for implementing the authorised protocol, such as the personal data of investigators. The categories of personal data to be collected

authorised protocol. Regulation (EU) No 536/2014 should be amended to establish specific safeguards for the processing of personal data, including genetic data or data concerning health, in compliance with Article 9(2), points (i) and (j), of Regulation (EU) 2016/679. For instance, it should require informed consent to participate in the clinical trial, as well as to maintain confidentiality of records and personal data of participants. The protocol should specify further appropriate safeguards such as specific technical and organisational measures that should be employed, including pseudonymisation, integrity and confidentiality controls, encryption and access restrictions. In addition, any clinical trial should be subject to ethical review.

and processed in the context of a specific clinical trial should be specified in the authorised protocol. Regulation (EU) No 536/2014 should be amended to establish specific safeguards for the processing of personal data, including genetic data or data concerning health, in compliance with Article 9(2), points (i) and (j), of Regulation (EU) 2016/679. For instance, it should require informed consent to participate in the clinical trial, as well as to maintain confidentiality of records and personal data of participants. The protocol should specify further appropriate safeguards such as specific technical and organisational measures that should be employed, including pseudonymisation, integrity and confidentiality controls, encryption and access restrictions. In addition, any clinical trial should be subject to ethical review.

Or. ro

Amendment 1019
Christine Anderson

Proposal for a regulation
Recital 152 a (new)

Text proposed by the Commission	*Amendment*
	(152a) Article 9(4) of Regulation (EU) 2016/679 expressly allows Member States to maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health. This Regulation should not remove that possibility in the context of clinical trials, in particular given the sensitivity of genetic and health data and the ethical diversity of Member States' legal traditions.

Or. en

Amendment 1020
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 153

Text proposed by the Commission	*Amendment*
(153) Personal data which is collected and processed under each authorised protocol in accordance with Regulation (EU) No 536/2014 as amended by this Regulation may be further processed by the same controller for the purposes of other clinical trials, conducted in accordance with Regulation (EU) No 536/2014. Such data may include names, contact details, health and genetic data of subjects. It should also be possible to further process such personal data by the same controller for scientific research purposes.	(153) Personal data which is collected and processed under each authorised protocol in accordance with Regulation (EU) No 536/2014 as amended by this Regulation may be further processed by the same controller for the purposes of other clinical trials, conducted in accordance with Regulation (EU) No 536/2014***, but with the consent of the data subjects***. Such data may include names, contact details, health and genetic data of subjects. It should also be possible to further process such personal data by the same controller for scientific research purposes***, as well as to protect data from theft or from being used for other purposes***.

Or. ro

Amendment 1021
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 156

Text proposed by the Commission	*Amendment*
(156) Regulation (EU) No 536/2014 outlines the responsibilities of Member States in designating competent authorities and ethics committees for regulatory activities, including oversight. To perform their roles as required by the provisions of this Regulation amending Regulation (EU) No 536/2014, these competent authorities and responsible ethics committees should be vested in the necessary powers, have at their disposal qualified personnel and sufficient resources to perform their duties effectively. Regulation (EU) 536/2014	(156) Regulation (EU) No 536/2014 outlines the responsibilities of Member States in designating competent authorities and ethics committees for regulatory activities, including oversight. To perform their roles as required by the provisions of this Regulation amending Regulation (EU) No 536/2014, these competent authorities and responsible ethics committees should be vested in the necessary powers, have at their disposal qualified personnel***, experience in the field corresponding to the specific requirements*** and sufficient

emphasizes the importance of communication and coordination to ensure consistent and efficient regulatory actions within Member States. It is also essential to define how the Commission will verify the correct implementation of the law by the competent authorities. Regulation (EU) No 536/2014 should be amended accordingly.	resources to perform their duties effectively. Regulation (EU) 536/2014 emphasizes the importance of communication and coordination to ensure consistent and efficient regulatory actions within Member States. It is also essential to define how the Commission will verify the correct implementation of the law by the competent authorities. Regulation (EU) No 536/2014 should be amended accordingly.

Or. ro

Amendment 1022
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 157

Text proposed by the Commission	*Amendment*
(157) The integration of AI in clinical trials presents opportunities to enhance the clinical trials' design, execution, and oversight. This technological advancement offers substantial benefits to clinical trial sponsors, regulators, and ultimately patients. Among the possible enhancements are improved endpoint determination, advanced statistical analysis, optimized patient selection, enhanced data handling and analysis. While AI tools aim to accelerate the development of medicinal products, it is imperative that their use in clinical trials adheres to applicable legislation. This includes, when applicable, compliance with Regulation (EU) 2024/1689, Regulation (EU) 2017/746, Regulation (EU) 2017/745 and Regulation (EU) 2016/679.	(157) The integration of AI in clinical trials presents opportunities to enhance the clinical trials' design, execution, and oversight. This technological advancement offers substantial benefits to clinical trial sponsors, regulators, and ultimately patients. Among the possible enhancements are improved endpoint determination, advanced statistical analysis, optimized patient selection, enhanced data handling and analysis. While AI tools aim to accelerate the development of medicinal products, it is imperative that their use in clinical trials adheres to applicable legislation. This includes, when applicable, compliance with Regulation (EU) 2024/1689, Regulation (EU) 2017/746, Regulation (EU) 2017/745 and Regulation (EU) 2016/679. ***The application of requirements related to the use of AI in clinical trials should be proportionate to the level of risk posed to patient safety and to the reliability of clinical trial outcomes. In particular, not all uses of AI in clinical trials should be subject to the same regulatory or documentation***

requirements, and only those uses that have a meaningful impact on patient safety or regulatory decision-making should be required to be specifically described in the clinical trial protocol.

Or. en

Amendment 1023
András Tivadar Kulja

Proposal for a regulation
Recital 157

Text proposed by the Commission	*Amendment*
(157) The integration of AI in clinical trials presents opportunities to enhance the clinical trials' design, execution, and oversight. This technological advancement offers substantial benefits to clinical trial sponsors, regulators, and ultimately patients. Among the possible enhancements are improved endpoint determination, advanced statistical analysis, optimized patient selection, enhanced data handling and analysis. While AI tools aim to accelerate the development of medicinal products, it is imperative that their use in clinical trials adheres to applicable legislation. This includes, when applicable, compliance with Regulation (EU) 2024/1689, Regulation (EU) 2017/746, Regulation (EU) 2017/745 and Regulation (EU) 2016/679.	(157) The integration of AI in clinical trials presents opportunities to enhance the clinical trials' design, execution, and oversight. This technological advancement offers substantial benefits to clinical trial sponsors, regulators, and ultimately patients. Among the possible enhancements are improved endpoint determination, advanced statistical analysis, optimized patient selection, enhanced data handling and analysis. While AI tools aim to accelerate the development of medicinal products, it is imperative that their use in clinical trials adheres to applicable legislation. This includes, when applicable, compliance with Regulation (EU) 2024/1689, Regulation (EU) 2017/746, Regulation (EU) 2017/745 and Regulation (EU) 2016/679. ***The application of requirements related to the use of AI in clinical trials should be proportionate to the level of risk posed to patient safety and to the reliability of clinical trial outcomes. AI in clinical trials that have a meaningful impact on patient safety or regulatory decision-making should be required to be specifically described in the clinical trial protocol.***

Or. en

Amendment 1024
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 157

Text proposed by the Commission	*Amendment*
(157) The integration of AI in clinical trials presents opportunities to enhance the clinical trials' design, execution, and oversight. This technological advancement offers substantial benefits to clinical trial sponsors, regulators, and ultimately patients. Among the possible enhancements are improved endpoint determination, advanced statistical analysis, optimized patient selection, enhanced data handling and analysis. While AI tools aim to accelerate the development of medicinal products, it is imperative that their use in clinical trials adheres to applicable legislation. This includes, when applicable, compliance with Regulation (EU) 2024/1689, Regulation (EU) 2017/746, Regulation (EU) 2017/745 and Regulation (EU) 2016/679.	(157) The integration of AI in clinical trials presents opportunities to enhance the clinical trials' design, execution, and oversight. This technological advancement offers substantial benefits to clinical trial sponsors, regulators, and ultimately patients***, but it should not be defining and should not avoid trials being conducted using classic methods***. Among the possible enhancements are improved endpoint determination, advanced statistical analysis, optimized patient selection, enhanced data handling and analysis. While AI tools aim to accelerate the development of medicinal products, it is imperative that their use in clinical trials adheres to applicable legislation. This includes, when applicable, compliance with Regulation (EU) 2024/1689, Regulation (EU) 2017/746, Regulation (EU) 2017/745 and Regulation (EU) 2016/679.

Or. ro

Amendment 1025
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 157

Text proposed by the Commission	*Amendment*
(157) The integration of AI in clinical trials presents opportunities to enhance the clinical trials' design, execution, and oversight. This technological advancement	(157) The integration of AI in clinical trials presents opportunities to enhance the clinical trials' design, execution, and oversight. This technological advancement

offers substantial benefits to clinical trial sponsors, regulators, and ultimately patients. Among the possible enhancements are improved endpoint determination, advanced statistical analysis, optimized patient selection, enhanced data handling and analysis. While AI tools aim to accelerate the development of medicinal products, it is imperative that their use in clinical trials adheres to applicable legislation. This includes, when applicable, compliance with Regulation (EU) 2024/1689, Regulation (EU) 2017/746, Regulation (EU) 2017/745 and Regulation (EU) 2016/679.	offers substantial benefits to clinical trial sponsors, regulators, and ultimately patients. Among the possible enhancements are improved endpoint determination, advanced statistical analysis, optimized patient selection, enhanced data handling and analysis***, without compromising privacy rights***. While AI tools aim to accelerate the development of medicinal products, it is imperative that their use in clinical trials adheres to applicable legislation. This includes, when applicable, compliance with Regulation (EU) 2024/1689, Regulation (EU) 2017/746, Regulation (EU) 2017/745 and Regulation (EU) 2016/679.

Or. en

Amendment 1026
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 158

Text proposed by the Commission	*Amendment*
(158) Sponsors hold the responsibility to evaluate the potential impact and risk of AI tools on patient safety based on guidelines. Untested systems may introduce gender and other biases and errors, risking unreliable outcomes or failures in interpreting medical data accurately. Such risks could lead to misdiagnosis, incorrect treatment, or inaccurate patient selection, especially hazardous in extensive clinical trials with numerous participants. The guidelines on the developments and deployment of AI tools developed by the Agency, in cooperation with the Clinical Trials Coordination and Advisory Group, and as appropriate, with other expert groups established under Union law, should assist the sponsors, national competent authorities and ethics committees in assessment of AI tools	(158) Sponsors hold the responsibility to evaluate the potential impact and risk of AI tools on patient safety based on guidelines. Untested systems may introduce gender and other biases and errors, risking unreliable outcomes or failures in interpreting medical data accurately. Such risks could lead to misdiagnosis, incorrect treatment, or inaccurate patient selection, especially hazardous in extensive clinical trials with numerous participants. The guidelines on the developments and deployment of AI tools developed by the Agency, in cooperation with the Clinical Trials Coordination and Advisory Group, and as appropriate, with other expert groups established under Union law ***as well as industry representatives***, should assist the sponsors, national competent authorities and ethics committees in

benefits and risks in the context of the lifecycle of clinical trials.	assessment of AI tools benefits and risks in the context of the lifecycle of clinical trials. ***Such assessment should follow a risk-based approach, taking into account the specific function and impact of the AI tool within the clinical trial.***

Or. en

Amendment 1027
András Tivadar Kulja

Proposal for a regulation
Recital 158

Text proposed by the Commission	*Amendment*
(158) Sponsors hold the responsibility to evaluate the potential impact and risk of AI tools on patient safety based on guidelines. Untested systems may introduce gender and other biases and errors, risking unreliable outcomes or failures in interpreting medical data accurately. Such risks could lead to misdiagnosis, incorrect treatment, or inaccurate patient selection, especially hazardous in extensive clinical trials with numerous participants. The guidelines on the developments and deployment of AI tools developed by the Agency, in cooperation with the Clinical Trials Coordination and Advisory Group, and as appropriate, with other expert groups established under Union law, should assist the sponsors, national competent authorities and ethics committees in assessment of AI tools benefits and risks in the context of the lifecycle of clinical trials.	(158) Sponsors hold the responsibility to evaluate the potential impact and risk of AI tools on patient safety based on guidelines. Untested systems may introduce gender and other biases and errors, risking unreliable outcomes or failures in interpreting medical data accurately. Such risks could lead to misdiagnosis, incorrect treatment, or inaccurate patient selection, especially hazardous in extensive clinical trials with numerous participants. The guidelines on the developments and deployment of AI tools developed by the Agency, in cooperation with the Clinical Trials Coordination and Advisory Group, and as appropriate, with other expert groups established under Union law, should assist the sponsors, national competent authorities and ethics committees in assessment of AI tools benefits and risks in the context of the lifecycle of clinical trials. ***Such assessment should follow a risk-based approach, taking into account the specific function and impact of the AI tool within the clinical trial.***

Or. en

Amendment 1028
Sirpa Pietikäinen

Proposal for a regulation
Recital 158

Text proposed by the Commission	*Amendment*
(158) Sponsors hold the responsibility to evaluate the potential impact and risk of AI tools on patient safety based on guidelines. Untested systems may introduce gender and other biases and errors, risking unreliable outcomes or failures in interpreting medical data accurately. Such risks could lead to misdiagnosis, incorrect treatment, or inaccurate patient selection, especially hazardous in extensive clinical trials with numerous participants. The guidelines on the developments and deployment of AI tools developed by the Agency, in cooperation with the Clinical Trials Coordination and Advisory Group, and as appropriate, with other expert groups established under Union law, should assist the sponsors, national competent authorities and ethics committees in assessment of AI tools benefits and risks in the context of the lifecycle of clinical trials.	(158) Sponsors hold the responsibility to evaluate the potential impact and risk of AI tools on patient safety based on guidelines. Untested systems may introduce***, perpetuate or amplify sex,*** gender and other biases and errors, risking unreliable outcomes or failures in interpreting medical data accurately. Such risks could lead to misdiagnosis, incorrect treatment, or inaccurate patient selection, especially hazardous in extensive clinical trials with numerous participants. The guidelines on the developments and deployment of AI tools developed by the Agency, in cooperation with the Clinical Trials Coordination and Advisory Group, and as appropriate, with other expert groups established under Union law, should assist the sponsors, national competent authorities and ethics committees in assessment of AI tools benefits and risks in the context of the lifecycle of clinical trials.

Or. en

Amendment 1029
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 158 a (new)

Text proposed by the Commission	*Amendment*
	(158a) The risk-based approach to AI use, as set down in Regulation (EU) 2024/1689, is the basis for a proportionate and effective set of binding rules. It is important to recall the 2019 Ethics Guidelines for Trustworthy AI developed

by the independent AI HLEG appointed by the Commission. In those guidelines, the AI HLEG developed seven non-binding ethical principles for AI which are intended to help ensure that AI is trustworthy and ethically sound. The seven principles include human agency and oversight; technical robustness and safety; privacy and data governance; transparency; diversity, non-discrimination and fairness; societal and environmental well-being and accountability. Without prejudice to the legally binding requirements of this Regulation and any other applicable Union law, those guidelines contribute to the design of coherent, trustworthy and human-centric AI, in line with the Charter of Fundamental Rights of the European Union and with the values on which the Union is founded. According to the guidelines of the AI HLEG, human agency and oversight means that AI systems are developed and used as a tool that serves people, respects human dignity and personal autonomy, and that is functioning in a way that can be appropriately controlled and overseen by humans. Technical robustness and safety means that AI systems are developed and used in a way that allows robustness in the case of problems and resilience against attempts to alter the use or performance of the AI system so as to allow unlawful use by third parties, and minimise unintended harm. Privacy and data governance means that AI systems are developed and used in accordance with privacy and data protection rules, while processing data that meets high standards in terms of quality and integrity. Transparency means that AI systems are developed and used in a way that allows appropriate traceability and explainability, while making humans aware that they communicate or interact with an AI system, as well as duly informing deployers of the capabilities and limitations of that AI system and affected persons about their rights.

Diversity, non-discrimination and fairness means that AI systems are developed and used in a way that includes diverse actors and promotes equal access, gender equality and cultural diversity, while avoiding discriminatory impacts and unfair biases that are prohibited by Union or national law.

Or. en

Amendment 1030
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 159 a (new)

Text proposed by the Commission	*Amendment*
	(159a) Advanced therapy medicinal products prepared under the hospital exemption provide important therapeutic options for patients with high unmet medical needs, in particular, but not only, in rare, ultra-rare or paediatric conditions. The application of that exemption should continue to ensure a high level of quality, safety, pharmacovigilance and patient protection, while preserving its patient-specific nature. Without prejudice to the hospital exemption regime laid down in Union pharmaceutical law, to Member States' competences under Article 168(7) TFEU and to the compromises reached in the pharmaceutical reform, cooperation between Member States, academic centres, hospitals and relevant

Or. en

Amendment 1031
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation

Recital 161

Text proposed by the Commission	*Amendment*
(161) Advances in biotechnology bring new opportunities for the development of veterinary ***medicinal products***, including the possibility to develop vaccines with improved safety and efficacy profiles in a much shorter timeframe. The possibility to deploy and use vaccines quickly is essential to react to outbreaks of certain animal diseases thereby reducing the risks for human health, contributing to animal welfare and reducing economic losses for farmers.	(161) Advances in biotechnology bring new opportunities for the development of ***vaccines for human and*** veterinary ***use***, including the possibility to develop vaccines with improved safety and efficacy profiles in a much shorter timeframe. The possibility to deploy and use vaccines quickly is essential to react to outbreaks of ***infectious and*** certain animal diseases thereby reducing the risks for human health, contributing to animal ***health and*** welfare and reducing ***negative socio-economic impacts including*** economic losses for farmers. ***Zoonotic diseases and antimicrobial resistance represent incresingly significant and interconnected threats to public health, animal health and economic security in the Union, making it necessary to invest in pandemic preparedness, related procurement and EU manufacturing of diagnostics and medical countermeasures. Effective vaccination strategies, both in the Union and as part of the EU mandate on global health, in both humans and animals can reduce the burden of infectious diseases, limit pathogen transmission across species and reduce the need for antimicrobial use. The Union should therefore promote strategic biotechnology projects that support the development, manufacturing and authorisation of vaccines addressing zoonotic, transboundary and emerging infectious diseases, consistent with the 'One Health' approach and the objective of strengthening the Union's preparedness and resilience against future health threats objectives including global health.***

Or. en

Justification

The wording of Recital (161) is modified and expanded to include vaccines for human use. The rationale for veterinary vaccines equally applies to human vaccines, and there is no justification for excluding them.

Amendment 1032
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 161

Text proposed by the Commission	*Amendment*
(161) Advances in biotechnology bring new opportunities for the development of veterinary medicinal products, including the possibility to develop vaccines with improved safety and efficacy profiles in a much shorter timeframe. The possibility to deploy and use vaccines quickly is essential to react to outbreaks of certain animal diseases thereby reducing the risks for human health, contributing to animal welfare and reducing economic losses for farmers.	(161) Advances in biotechnology bring new opportunities for the development of veterinary medicinal products, including the possibility to develop vaccines with improved safety and efficacy profiles in a much shorter timeframe. The possibility to deploy and use vaccines quickly is essential to react to outbreaks of certain animal diseases thereby reducing the risks for human health, contributing to animal welfare and reducing economic losses for farmers. ***Zoonotic diseases and antimicrobial resistance represent major and interconnected threats to public health, animal health and economic security in the Union. Effective vaccination strategies in both humans and animals can reduce the burden of infectious diseases, limit pathogen transmission across species and decrease the need for antimicrobial use. The Union should therefore promote strategic biotechnology projects that support the development, manufacturing and authorisation of vaccines addressing zoonotic, transboundary and emerging infectious diseases, consistent with the 'One Health' approach and the objective of strengthening the Union's preparedness and resilience against future health threats.***

Or. en

Amendment 1033
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 161

Text proposed by the Commission	*Amendment*
(161) Advances in biotechnology bring new opportunities for the development of veterinary medicinal products, including the possibility to develop vaccines with improved safety and efficacy profiles in a much shorter timeframe. The possibility to deploy and use vaccines quickly is essential to react to outbreaks of certain animal diseases thereby reducing the risks for human health, contributing to animal welfare and reducing economic losses for farmers.	(161) Advances in biotechnology bring new opportunities for the development of veterinary medicinal products, including the possibility to develop vaccines with improved safety and efficacy profiles in a much shorter timeframe. The possibility to deploy and use vaccines quickly is essential to react to outbreaks of certain animal diseases thereby reducing the risks for human health, contributing to animal welfare and reducing economic losses for farmers. ***Zoonotic diseases and antimicrobial resistance represent major and interconnected threats to public health, animal health and economic security in the Union. Effective vaccination strategies in both humans and animals can reduce the burden of infectious diseases, limit pathogen transmission across species and decrease the need for antimicrobial use. The Union should therefore promote strategic biotechnology projects that support the development, manufacturing and authorisation of vaccines addressing zoonotic, transboundary and emerging infectious diseases, consistent with the One Health approach and the objective of strengthening the Union's preparedness and resilience against future health threats.***

Or. en

Amendment 1034
Margarita de la Pisa Carrión, András Gyürk, Viktória Ferenc, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Recital 161

Text proposed by the Commission	*Amendment*
(161) Advances in biotechnology bring new opportunities for the development of veterinary medicinal products, including the possibility to develop vaccines with improved safety and efficacy profiles in a much shorter timeframe. The possibility to deploy and use vaccines quickly is essential to react to outbreaks of certain animal diseases thereby reducing the risks for human health, contributing to animal welfare and reducing economic losses for farmers.	(161) Advances in biotechnology bring new opportunities for the development of veterinary medicinal products, including the possibility to develop vaccines with improved safety and efficacy profiles in a much shorter timeframe. The possibility to deploy and use vaccines quickly is essential to react to outbreaks of certain animal diseases thereby reducing the risks for human health, contributing to animal welfare and reducing economic losses for farmers. ***In order to further safeguard Member States' response to zoonotic diseases, the Union should promote strategic biotechnology projects that support the research, development, manufacturing and authorisation of novel antimicrobial drugs and agents, which faces significant scientific and regulatory impasses. The design and access to market of said novel antimicrobial products would counter the risk of existing antimicrobial resistant strains.***

Or. en

Amendment 1035
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 161

Text proposed by the Commission	*Amendment*
(161) Advances in biotechnology bring new opportunities for the development of veterinary medicinal products, including the possibility to develop vaccines with improved safety and efficacy profiles in a much shorter timeframe. The possibility to deploy ***and use*** vaccines quickly is essential to react to outbreaks of certain animal diseases thereby reducing the risks	(161) Advances in biotechnology bring new opportunities for the development of veterinary medicinal products, including the possibility to develop vaccines with improved safety and efficacy profiles in a much shorter timeframe. The possibility to deploy vaccines ***to all farmers, without discrimination and without specific conditions, and to use them*** quickly is

for human health, contributing to animal welfare and reducing economic losses for farmers.	essential to react ***as quickly as possible*** to outbreaks of certain animal diseases thereby reducing the risks for human health, contributing to animal welfare and reducing economic losses for farmers ***across all Member States***.

Or. ro

Amendment 1036
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 161

Text proposed by the Commission	*Amendment*
(161) Advances in biotechnology bring new opportunities for the development of veterinary medicinal products, including the possibility to develop vaccines with improved safety and efficacy profiles in a much shorter timeframe. The possibility to deploy and use vaccines quickly is essential to react to outbreaks of ***certain animal*** diseases thereby reducing the risks for human health, contributing to animal welfare and reducing economic losses for farmers**.**	(161) Advances in biotechnology bring new opportunities for the development of veterinary medicinal products ***and vaciness***, including the possibility to develop vaccines with improved safety and efficacy profiles in a much shorter timeframe. The possibility to deploy and use vaccines quickly is essential to react to outbreaks of ***infection*** diseases thereby reducing the risks for human health, contributing to animal ***health and*** welfare and reducing economic losses for farmers

Or. en

Amendment 1037
Giorgio Gori

Proposal for a regulation
Recital 161 a (new)

Text proposed by the Commission	*Amendment*
	(161a) Epidemiological surveillance and vaccine effectiveness data are essential for vaccine research and development, and for ensuring resilience and preparedness. Persistent data gaps and lack of timeliness

across the Union continue to affect public health decision-making and hinder innovation, with the the risk of remaining reliant on ex-EU data sources hindering the Union's capabilities. It is critical to ensure secure, independent and timely access to robust, high-quality epidemiological and vaccines effectiveness data, supporting preparedness, response and the resilience of immunisation systems. In this context, the respective competences of Member States, the Commission, other Union bodies and agencies, and relevant third countries and international organisations, in particular the WHO, must be respected.

Or. en

Amendment 1038
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 161 a (new)

Text proposed by the Commission	*Amendment*
	(161a) Epidemiological surveillance and vaccine effectiveness data are essential for vaccine research and development, and for ensuring resilience and preparedness. Persistent data gaps and lack of timeliness across the Union continue to affect public health decision-making and hinder innovation, with the the risk of remaining reliant on ex-EU data sources hindering the Union's capabilities. It is critical to ensure secure, independent and timely access to robust, high-quality epidemiological and vaccines effectiveness data, supporting preparedness, response and the resilience of immunisation systems. In this context, the respective competences of Member States, the Commission, other Union bodies and agencies, and relevant third countries and international organisations,

in particular the WHO, must be respected.

Or. en

Amendment 1039
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Martin Hojsík

Proposal for a regulation
Recital 161 a (new)

Text proposed by the Commission	*Amendment*
	(161a) Epidemiological surveillance and vaccine effectiveness data are essential for vaccine research and development, and for ensuring resilience and preparedness. Persistent data gaps and lack of timeliness across the Union continue to affect public health decision-making and hinder innovation, with the the risk of remaining reliant on ex-EU data sources hindering the Union's capabilities. It is critical to ensure secure, independent and timely access to robust, high-quality epidemiological and vaccines effectiveness data, supporting preparedness, response and the resilience of immunisation systems. In this context, the respective competences of Member States, the Commission, other Union bodies and agencies, and relevant third countries and international organisations, in particular the WHO, must be respected.

Or. en

Justification

Persistent gaps in epidemiological and vaccine effectiveness data hinder public health decision-making, innovation and preparedness. Strengthening the Union's data capabilities is necessary to enhance resilience, reduce reliance on external data sources, and support effective immunisation systems.

Amendment 1040
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 166

Text proposed by the Commission	*Amendment*
(166) Veterinary medicinal products developed by means of biotechnology processes to diagnose, treat or prevent zoonotic diseases should be entitled to an extra year of supplementary protection certificate ('SPC') in order to support their development.	***deleted***

Or. en

Amendment 1041
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 166

Text proposed by the Commission	*Amendment*
(166) Veterinary medicinal products developed by means of biotechnology processes to diagnose, treat or prevent zoonotic diseases should be entitled to an extra year of supplementary protection certificate ('SPC') in order to support their development.	***deleted***

Or. en

Amendment 1042
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 166 a (new)

Text proposed by the Commission	*Amendment*
	(166a) A substantial proportion of emerging infectious diseases affecting humans originate in animals. The

increasing frequency of zoonotic disease outbreaks highlights the need for an integrated approach to preparedness and response that recognises the interdependence of human, animal and environmental health. In accordance with the 'One Health' approach, the Union should support the development, manufacturing and deployment of innovative vaccines and other biotechnology solutions addressing zoonotic and emerging infectious diseases in both humans and animals. Vaccination of animals plays an important role in preventing infectious diseases, reducing the need for antimicrobial treatments and supporting efforts to combat antimicrobial resistance.

Or. en

Amendment 1043
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 166 a (new)

Text proposed by the Commission	*Amendment*
	(166a) A substantial proportion of emerging infectious diseases affecting humans originate in animals. The increasing frequency of zoonotic disease outbreaks highlights the need for an integrated approach to preparedness and response that recognises the interdependence of human, animal and environmental health. In accordance with the One Health approach, the Union should support the development, manufacturing and deployment of innovative vaccines and other biotechnology solutions addressing zoonotic and emerging infectious diseases in both humans and animals. Vaccination of animals plays an important role in preventing infectious diseases, reducing the need for antimicrobial treatments and

supporting efforts to combat antimicrobial resistance.

Or. en

Amendment 1044
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Recital 167

Text proposed by the Commission	*Amendment*
(167) Scientific and technical progress in biotechnology enables the development of new technologies, methods or products that may not fit into existing Union legislation. The lack of harmonised requirements is an impediment to the development, marketing and use of new concepts that may, however, bring benefit to animal healthcare. Regulatory sandboxes may be established to facilitate the development, placing on the market or use of innovative technologies, methods or products related to animal health which are directly or indirectly related to the development, manufacturing or use of veterinary medicinal products under conditions that ensure protection of animal and public health as well as the environment. A regulatory sandbox should only be established if there is no Union legislation governing the marketing and use of the relevant technology, method or product.	***deleted***

Or. en

Amendment 1045
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 167

Text proposed by the Commission	*Amendment*
(167) Scientific and technical progress in biotechnology enables the development of new technologies, methods or products that may not fit into existing Union legislation. The lack of harmonised requirements is an impediment to the development, marketing and use of new concepts that may, however, bring benefit to animal healthcare. Regulatory sandboxes may be established to facilitate the development, placing on the market or use of innovative technologies, methods or products related to animal health which are directly or indirectly related to the development, manufacturing or use of veterinary medicinal products under conditions that ensure protection of animal and public health as well as the environment. A regulatory sandbox should only be established if there is no Union legislation governing the marketing and use of the relevant technology, method or product.	***deleted***

Or. en

Amendment 1046
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 168

Text proposed by the Commission	*Amendment*
(168) A regulatory sandbox may be established by the Commission, by way of an implementing act following a recommendation of the Agency which should analyse expected potential benefits and risks as well as existing regulatory challenges. Technical and scientific requirements for the technologies, methods or products under the regulatory sandbox and procedures should be developed and published by the Agency.	***deleted***

The Agency should ensure that the requirements and procedures it develops are proportionate and are adapted to the specific risks. A regulatory sandbox may be terminated at any time where, following the identification of negative impacts on animal or public health or the environment, the benefit-risk balance becomes negative and there are no satisfactory risk mitigation measures that could be implemented.

Or. en

Amendment 1047
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Recital 168

Text proposed by the Commission	*Amendment*
(168) A regulatory sandbox may be established by the Commission, by way of an implementing act following a recommendation of the Agency which should analyse expected potential benefits and risks as well as existing regulatory challenges. Technical and scientific requirements for the technologies, methods or products under the regulatory sandbox and procedures should be developed and published by the Agency. The Agency should ensure that the requirements and procedures it develops are proportionate and are adapted to the specific risks. A regulatory sandbox may be terminated at any time where, following the identification of negative impacts on animal or public health or the environment, the benefit-risk balance becomes negative and there are no satisfactory risk mitigation measures that could be implemented.	***deleted***

Or. en

Amendment 1048
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 169

Text proposed by the Commission	*Amendment*
(169) Technologies, methods or products developed under a regulatory sandbox should only be placed on the market or used on the basis of an authorisation granted by the Commission. Depending on the specific characteristics of the products concerned, a class authorisation to market or use technologies, methods or products may be possible. Member States should be empowered to take interim measures where serious risks to animal or public health or the environment are identified. In such cases, Member States should swiftly inform the Agency.	(169) Technologies, methods or products developed under a regulatory sandbox should only be placed on the market or used on the basis of an authorisation granted by the Commission ***in accordance with applicable Union law***. Depending on the specific characteristics of the products concerned, a class authorisation to market or use technologies, methods or products may be possible. Member States should be empowered to take interim measures where serious risks to animal or public health or the environment are identified. In such cases, Member States should swiftly inform the Agency.

Or. en

Amendment 1049
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 170

Text proposed by the Commission	*Amendment*
(170) To ensure legal certainty, the termination of a regulatory sandbox should not affect the validity of the authorisations to place on the market or use technologies, methods or products already granted, unless the regulatory sandbox has been terminated on grounds related to the protection of public or animal health or the environment.	***deleted***

Or. en

Amendment 1050
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Recital 170

Text proposed by the Commission	*Amendment*
(170) To ensure legal certainty, the termination of a regulatory sandbox should not affect the validity of the authorisations to place on the market or use technologies, methods or products already granted, unless the regulatory sandbox has been terminated on grounds related to the protection of public or animal health or the environment.	***deleted***

Or. en

Amendment 1051
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 172

Text proposed by the Commission	*Amendment*
(172) The field of substances of human origin is characterised by rapid scientific and technological innovation, giving rise to health biotechnology approaches that may present scientific or regulatory challenges under existing legal requirements. To support the development of such innovations at early stages while maintaining public health protection, Member States should be able to establish regulatory sandboxes for substances of human origin that cannot yet be developed in full compliance with the requirements of Regulation (EU) 2024/1938, provided that the innovative characteristics or methods are expected to contribute distinctively to quality, safety,	***deleted***

effectiveness, or patient access to treatment. The sandbox activities should enable a discussion on the development of common approaches and the potential adaptation of legislative frameworks based on accumulated experience. Any substances of human origin developed through regulatory sandboxes should only be distributed for human application when properly authorised, with initial authorisations limited to the regulatory sandbox duration. This framework should enable controlled experimentation with innovative regulatory approaches while preserving the essential safeguards for public health and safety. Regulation (EU)2024/1938 should be amended accordingly.

Or. en

Amendment 1052
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Recital 172

Text proposed by the Commission	*Amendment*
(172) The field of substances of human origin is characterised by rapid scientific and technological innovation, giving rise to health biotechnology approaches that may present scientific or regulatory challenges under existing legal requirements. ***To support the development of such innovations at early stages while maintaining public health protection, Member States should be able to establish regulatory sandboxes for substances of human origin that cannot yet be developed in full compliance with the requirements of Regulation (EU) 2024/1938, provided that the innovative characteristics or methods are expected to contribute distinctively to quality, safety, effectiveness, or patient access to treatment. The sandbox activities should***	(172) The field of substances of human origin is characterised by rapid scientific and technological innovation, giving rise to health biotechnology approaches that may present scientific or regulatory challenges under existing legal requirements.

enable a discussion on the development of common approaches and the potential adaptation of legislative frameworks based on accumulated experience. Any substances of human origin developed through regulatory sandboxes should only be distributed for human application when properly authorised, with initial authorisations limited to the regulatory sandbox duration. This framework should enable controlled experimentation with innovative regulatory approaches while preserving the essential safeguards for public health and safety. Regulation (EU)2024/1938 should be amended accordingly.

Or. en

Amendment 1053
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 173

Text proposed by the Commission	*Amendment*
(173) The regulatory sandboxes in the field of substances of human origin should be conducted under the supervision of the concerned SoHO competent authorities, and, where relevant, competent authorities under other Union and Member State legislation concerned. The latter authorities should be in particular involved where the preparation of the SoHO requires steps using products regulated under another Union legislative framework, or where SoHO is presented as a therapy together with products regulated under another such Union framework.	***deleted***

Or. en

Amendment 1054
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 173 a (new)

Text proposed by the Commission	*Amendment*
	(173a) Regulatory sandboxes are designed to accommodate innovation that does not correspond to a single pre-established regulatory regime. Certain technologies applied to human organs intended for transplantation — including ex vivo/ex-situ perfusion, gene therapy, and cellular, organoid-based or other reconstruction, remodelling or repair techniques — fall precisely into such a gap, being classifiable, depending on the framework applied, as an organ under Directive 2010/53/EU, as a substance of human origin under Regulation (EU) 2024/1938, or as a medicinal product or Advanced Therapy Medicinal Product under Regulation (EC) No 1394/2007 and Directive 2001/83/EC.

Or. en

Amendment 1055
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 173 c (new)

Text proposed by the Commission	*Amendment*
	(173c) Consistent with the fundamental principle, reflected in Article 3 of the Charter of Fundamental Rights of the European Union, that the human body and its parts are not to be a source of financial gain, a human organ donated for transplantation does not lose that nature when it is subjected to a technological process intended to improve its function or the survival of the graft. Such a process should be assessed and,

where appropriate, authorised without removing the organ from the donation-and-transplantation system, from the allocation criteria established on medical and social grounds, or from societal stewardship over its use.

Or. en

Amendment 1056
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 173 e (new)

Text proposed by the Commission	*Amendment*
	(173e) No single existing framework is designed to evaluate a process applied to an organ while preserving the organ's legal status. A dedicated sandbox should therefore be established, coordinated by the SoHO Coordination Board (SCB) in cooperation with the competent authorities for organs designated under Directive 2010/53/EU, the European Medicines Agency (EMA), and the competent pharmaceutical authorities, drawing on the SCB's existing mandate under Regulation (EU) 2024/1938 to issue opinions on the regulatory status of substances, products and activities at the borderline between adjacent frameworks.

Or. en

Amendment 1057
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 173 g (new)

Text proposed by the Commission	*Amendment*
	(173g) The core regulatory tool available to assess such processes is a

proportionate, risk-based approach of the kind already embedded in Regulation (EU) 2024/1938. That approach should not be built from first principles: the Union has already developed, tested and applied a structured risk-based assessment methodology for substances of human origin — the European Good Tissue and Cells Practices, second edition (EuroGTP II) — originally created for tissues and cells and subsequently extended to blood-based preparations. The sandbox should mandate the adaptation of that same methodology to human organs, so that risk classification, the scope of clinical evidence required, and follow-up obligations are calibrated to the specific process applied rather than imported wholesale from the pharmaceutical framework.

Or. en

Amendment 1058
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 173 i (new)

Text proposed by the Commission	*Amendment*
	(173i) The outcome of that risk-based assessment should be an authorisation of a different legal nature from a marketing authorisation for a medicinal product: an authorisation of use, granted in respect of the process applied to the organ, and conditioned on outcome-monitoring and traceability obligations proper both to transplantation and to the technology concerned.

Or. en

Amendment 1059
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 173 k (new)

Text proposed by the Commission	*Amendment*
	(173k) The sandbox should also provide legal certainty for the externalisation or licensing of such processing services, on a case-by-case basis, without altering the non-commercial nature of the organ itself, in support of the Union's strategic autonomy objectives in biotechnology, including under the forthcoming Biotech Act.

Or. en

Amendment 1060
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 174

Text proposed by the Commission	*Amendment*
(174) In order to ensure uniform conditions for the implementation of this Regulation regarding the recognition by the Commission of high impact biotechnology strategic projects, the modalities for the processing of personal data necessary to achieve the purpose of such projects in the form of biotechnology data quality accelerators and the rules for the selection, composition, number of members, and functioning of the Foresight Panel for Emerging Health Innovation, implementing powers should be conferred on the Commission.	(174) In order to ensure uniform conditions for the implementation of this Regulation regarding the recognition by the Commission of high impact biotechnology strategic projects, the modalities for the processing of personal data necessary to achieve the purpose of such projects in the form of biotechnology data quality accelerators and the rules for the selection, composition, number of members, and functioning of the Foresight Panel for Emerging Health Innovation, implementing powers should be conferred on the Commission. ***Given the significance of those acts, the Commission should consult the Steering Group, relevant independent expert bodies, Member States, patient organisations, SME representatives, industry, ethics experts and, where relevant, European Reference Network coordinators.***

Or. en

Amendment 1061
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 174 a (new)

Text proposed by the Commission	*Amendment*
	(174a) The European Health Data Space provides the legal framework for the secondary use of health data for research and innovation. For rare and ultra-rare diseases, in which patients are few and dispersed across the Member States, the fragmentation of health data is a principal obstacle to diagnosis, research and therapeutic development. This Regulation should therefore support the integration of interoperable data standards across national health systems and the expert centres of the European Reference Networks, secure, privacy-preserving cross-border access to rare disease registries

Or. en

Amendment 1062
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 174 b (new)

Text proposed by the Commission	*Amendment*
	(174b) Newborn screening is among the most cost-effective secondary-prevention programmes in modern medicine, enabling the detection, before the onset of symptoms, of conditions and disorders for which advanced therapy medicinal products now exist. However, the panels

of conditions screened diverge substantially across the Member States. Early diagnosis is the precondition for early treatment, and there is a need for the adoption of Union guidelines to harmonise newborn screening and the integration of newborn screening data with the European Health Data Space to allow the secondary use of pseudonymised newborn screening data for research, surveillance and the validation of new screening targets. Because newborn screening data is genetic, relates to a minor and is generated in the absence of the consent of the data subject, its integration with the European Health Data Space requires privacy and governance calibrated to the exceptional sensitivity that provides for interoperability of national newborn screening registries with the European Health Data Space using harmonised data standards and reinforces consent.

Or. en

Amendment 1063
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 175

Text proposed by the Commission	*Amendment*
(175) In order to ensure uniform conditions for the implementation of this Regulation, implementing power should be conferred on the Commission to ***detail the criteria to clarify in what cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem and accelerate innovation, detail the criteria*** for the recognition of centres of excellence for advanced therapies, including advanced therapy medicinal product, establish procedural rules for the recognition of high	(175) In order to ensure uniform conditions for the implementation of this Regulation, implementing power should be conferred on the Commission to ***establish procedural rules*** for the recognition of centres of excellence for advanced therapies, including advanced therapy medicinal product, establish procedural rules for the recognition of high impact health biotechnology strategic projects and the format of the assessment report to be submitted by the designated authorities in relation to applications for recognition of

impact health biotechnology strategic projects and the format of the assessment report to be submitted by the designated authorities in relation to applications for recognition of high impact health biotechnology strategic projects, ***establish regulatory sandboxes for health biotechnology products and common principles, criteria and practical arrangements for the assessment of applications received from developers and for the establishment and supervision of the regulatory sandboxes and related sandbox plans.*** Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

high impact health biotechnology strategic projects, Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Or. en

Amendment 1064
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 176

Text proposed by the Commission	*Amendment*
(176) The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of modifying Annex I to this Regulation listing the biotechnology products of concern. It is of particular importance that the Commission ***carries*** out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making ***of 13 April 2016***. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the	(176) The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of modifying Annex I to this Regulation listing the biotechnology products of concern. It is of particular importance that the Commission ***carry*** out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement ***of 13 April 2016*** on Better Law-Making. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the

preparation of delegated acts.	preparation of delegated acts. ***In addition, it would be useful for Parliament and Council to receive periodic updates on the implementation of this Regulation.***

Or. ro

Amendment 1065
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 178 a (new)

Text proposed by the Commission	*Amendment*
	(178a) The evaluation of the Union framework for orphan and paediatric medicinal products has demonstrated that, while progress has been achieved, significant unmet medical need persists, in particular for very small patient populations affected by conditions characterised by a high unmet medical need for which no satisfactory therapeutic options are available [Joint Evaluation of Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use and Regulation (EC) No 141/2000 of the European Parliament and of the Council on orphan medicinal products, 11 August 2020, SWD(2020) 163 final]. It is therefore appropriate to complement existing Union frameworks, including the framework for orphan medicinal products, in order to address the specific challenges associated with such conditions.

Or. en

Justification

This and the following recitals relate to Chapter VIIa introduced in this report on biotechnology innovation for conditions affecting very small patient populations.These recitals and the relevant chapter address the following:Current regulatory practice and frameworks does not sufficiently support platform reuse for small-scale manufacturing for very small patient populations. There are several intersected regulatory challenges: •

First approval: it is extremely difficult to create sufficient and robust evidence for a treatment.• Second Approval: The benefit of ASOs are the "recycling" of the technological backbone - the platform or mechanism - that means you do not have to develop treatment number two entirely from scratch for a patient with a condition caused by a different gene-mutation than patient one. However, in the current framework, second approval is treated exactly like approval number one without any spillover of data or evidence from the first approval.• Business model: treatment for very small populations cannot base their business model on exclusivity rights because exclusivity only incentivize innovation when the market is big enough.• Link between MA/variation evidence and Market access: After Marketing authorization the second critical point to get to the patient is national health technology assessment (HTA) that is often determinant on market access.

Amendment 1066
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 178 b (new)

Text proposed by the Commission	*Amendment*
	(178b) Recent advances in molecular biology and biotechnology, including nucleic acid-based and sequence-targeted approaches, enable the development of medicinal products addressing defined molecular or genetic drivers of disease, including highly specific patient subgroups.

Or. en

Amendment 1067
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 178 c (new)

Text proposed by the Commission	*Amendment*
	(178c) Such approaches often rely on shared technological platforms, chemical structures, or mechanisms of action, while targeting distinct variants or indications. The application of standard development requirements to each individual product may result in disproportionate burdens,

unnecessary duplication of studies, and delays in patient access, without a commensurate benefit to public health.

Or. en

Amendment 1068
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 178 d (new)

Text proposed by the Commission	*Amendment*
	(178d) In order to strengthen the Union's competitiveness in biotechnology and to facilitate the development of innovative therapies for patients with unmet medical need, it is appropriate to provide for proportionate, science-based regulatory approaches that enable the efficient use of prior knowledge and platform-based evidence, while ensuring a high level of protection of public health.

Or. en

Amendment 1069
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 178 e (new)

Text proposed by the Commission	*Amendment*
	(178e) Such approaches should be accompanied by appropriate safeguards, including scientifically justified use of extrapolation and robust lifecycle evidence generation, in order to ensure that the quality, safety and efficacy of medicinal products are adequately demonstrated, while ensuring that the benefit-risk balance of the medicinal product is adequately demonstrated.

Or. en

Amendment 1070
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 178 f (new)

Text proposed by the Commission	*Amendment*
	(178f) For medicinal products intended to address conditions affecting very small patient populations, the systematic collection and appropriate sharing of post-authorisation data, including through Union-level infrastructures and initiatives such as the European Health Data Space, can strengthen the evidence base over time, support the use of prior knowledge and scientifically justified extrapolation, and reduce unnecessary duplication of studies.

Or. en

Amendment 1071
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 178 g (new)

Text proposed by the Commission	*Amendment*
	(178g) Given the specific challenges associated with very small patient populations and highly specialised or personalised therapies, targeted regulatory support and early scientific engagement, including, where appropriate, coordination with health technology assessment bodies, should be made available to developers.

Or. en

Amendment 1072
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 178 h (new)

Text proposed by the Commission	*Amendment*
	(178h) In certain cases, conditions affecting very small patient populations may be characterised by molecular or genetic variants that are specific to an individual patient. In such situations, the identification of a patient subgroup may rely on a well-characterised and scientifically substantiated molecular or genetic mechanism, notwithstanding the extremely limited number of patients concerned. It is therefore appropriate that the application of the provisions of this Chapter is not precluded solely on the basis of the size of the patient population, provided that the condition is defined on a scientifically justified molecular or genetic basis. At the same time, safeguards should be maintained to prevent the unjustified subdivision of broader conditions.

Or. en

Amendment 1073
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 178 i (new)

Text proposed by the Commission	*Amendment*
	(178i) Medicinal products intended to address conditions affecting very small patient populations may present particular challenges for the application of standard health technology assessment methodologies, which are often based on evidence generated in larger populations and on comparative analyses that may not be feasible in such contexts. In order to

facilitate effective patient access, it is appropriate that, where relevant, the evidence requirements and outcome measures applicable to such medicinal products are considered in a manner proportionate to their specific characteristics, and that, where possible, alignment between regulatory and health technology assessment considerations is sought at an early stage of development, in accordance with existing Union frameworks.

Or. en

Amendment 1074
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 178 j (new)

Text proposed by the Commission	*Amendment*
	(178j) Where a medicinal product qualifying under this Chapter is based on a validated technological platform, and a subsequent product differs from an already authorised product solely in the molecular or genetic variant addressed by its variable component, requiring the generation of an entirely new body of evidence and the completion of a new initial marketing authorisation procedure may be disproportionate to the limited nature of the change, in particular where the quality, manufacturing process and general safety profile of the platform have already been established. A comparable approach is already applied, under existing Union pharmaceutical law, to changes in the strain composition of human influenza vaccines, which are treated as variations to an existing marketing authorisation rather than as new medicinal products, in recognition of the fact that the manufacturing platform remains constant while the antigenic component varies. This principle is

consistent with, and should be given practical effect at the marketing authorisation stage through, the logic already reflected in Recital 143 concerning the use of certified platform technology master files to avoid the resubmission, in an investigational medicinal product dossier, of information already assessed at platform level. Whereas Recital 143 addresses this at the clinical trial stage, the non-binding guidance to be developed by the European Medicines Agency under Article 28 should extend the same proportionate treatment of platform-based products to the subsequent and otherwise unaddressed stage of marketing authorisation, including, where appropriate, for medicinal products qualifying under this Chapter. This Chapter does not itself alter the substantive evidentiary requirements for demonstrating quality, safety and efficacy, which continue to be assessed in a manner proportionate to feasibility in accordance with Articles 2 and 3.

Or. en

Amendment 1075
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 178 k (new)

Text proposed by the Commission	*Amendment*
	(178k) Medicinal products qualifying under this Chapter may, depending on their mechanism of action, fall within the scope of legislation governing the deliberate release of genetically modified organisms. Where such a product presents no or negligible environmental risk, the regulatory and administrative burden associated with a full environmental risk assessment may be disproportionate to the actual risk

involved, irrespective of whether the product is classified as an advanced therapy medicinal product. The risk-proportionate exemption from environmental risk assessment provided for in this Act in respect of certain investigational advanced therapy medicinal products containing genetically modified organisms should therefore be capable of extending, on the same basis of negligible environmental risk and verification by the Committee for Medicinal Products for Human Use, to other medicinal products qualifying under this Chapter, so that the applicable regulatory treatment reflects the environmental risk profile of the product rather than its product classification alone.

Or. en