



2025/0406(COD)

1.6.2026

DRAFT OPINION

of the Committee on the Environment, Climate and Food Safety

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

on the proposal for a regulation of the European Parliament and of the Council establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act) (COM(2025)1022 – C10-0363/2025 – 2025/0406(COD))

Rapporteur for opinion: Nicolás González Casares

PA_Legam

SHORT JUSTIFICATION

The amendments seek to strike an appropriate balance between fostering innovation in biotechnology and maintaining the high standards of consumer protection, environmental safety and scientific integrity that underpin Union legislation. While regulatory frameworks should be sufficiently agile to accommodate technological progress, innovation must develop within conditions that ensure transparency, accountability and public trust.

The inclusion of novel foods within regulatory sandboxes recognises that products reaching consumers directly should not be excluded from structured regulatory oversight merely because they are innovative. Similarly, enabling the Commission and relevant Union authorities to establish centralised regulatory sandboxes complements national initiatives, promotes consistency across the Single Market and facilitates access to specialised scientific expertise, while reducing fragmentation and ensuring a level playing field.

The proposed modification concerning exemptions from GMO requirements for Advanced Therapy Medicinal Products strengthens the evidence base of regulatory decisions by requiring applicants to provide a justification rather than relying solely on self-declarations. This proportionate safeguard enhances legal certainty, scientific robustness and public confidence without creating unnecessary barriers to innovation.

The proposed extension of supplementary protection mechanisms lacks a proper econometric impact assessment. Moreover, the use of such mechanisms to incentivise the development of veterinary medicinal products targeting zoonotic diseases is not supported by sufficient economic evidence demonstrating that additional exclusivity would effectively address the underlying market failures in this sector. While conditions linked to production in Europe may be viewed favourably in principle, demand for zoonotic vaccines is often episodic, outbreak-driven and highly dependent on public health circumstances, thereby limiting the incentive value of a fixed exclusivity extension. Veterinary vaccines also require rapid adaptation to emerging pathogens and circulating variants, making innovation dependent on regulatory flexibility and scientific responsiveness rather than prolonged protection of a specific product. As a result, extensions of intellectual property protection may be poorly suited to stimulating investment in this field.

More targeted policy instruments, including push incentives such as research grants, public-private partnerships and support for clinical development, as well as pull incentives such as advance purchase commitments, market guarantees and strategic procurement mechanisms, are better adapted to the specific characteristics of zoonotic vaccine development. A balanced push-pull approach would provide stronger and more predictable incentives for innovation while ensuring that public investment is aligned with public health preparedness, animal health objectives and societal needs.

The amendments concerning EFSA governance pursue a similar objective. A stronger role for EFSA in coordinating scientific panels may improve coherence and efficiency but should be accompanied by safeguards that preserve the independence, diversity and plurality of scientific expertise. Likewise, while pre-submission advice can help applicants prepare higher-quality

dossiers and support innovation, appropriate separation between advisory and assessment functions remains essential to avoid conflicts of interest and maintain confidence in the impartiality of risk assessments.

Taken together, these amendments reinforce an innovation-friendly regulatory framework that remains firmly grounded in scientific evidence, precaution, transparency and democratic accountability. They aim to ensure that technological advances deliver benefits to society while safeguarding human health, consumers, biodiversity and the environment.

AMENDMENT

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

Amendment 1

Proposal for a regulation

Recital 5

Text proposed by the Commission

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

Amendment

(5) Given the importance of health biotechnology amongst the other applications of biotechnology as referred to in recital (1), it is appropriate that this Regulation focusses on, and sets out specific measures for, the health dimension of biotechnology. To ensure the effectiveness of this Regulation, its scope of application should extend to health biotechnology in a comprehensive manner and cover health within the wide meaning of Article 168 TFEU on the protection of public health, ***as well as of Article 191 TFEU aiming at a high level of protection of the environment and human health in line with the 'One Health' approach and the precautionary principle.***

Or. en

Amendment 2

Proposal for a regulation

Recital 10

Text proposed by the Commission

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

Amendment

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

Directive 2010/63/EU sets the goal of full replacement of procedures on live animals for scientific and educational purposes as soon as scientifically possible, while applying the principle of replacement, reduction and refinement. In line with that objective, and taking into account the Commission roadmap towards phasing out animal testing, this Regulation should support the development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies (NAMs), where scientifically appropriate. Such NAMs, including human-based in vitro systems, organoids, organ-on-chip technologies, computational modelling and other advanced non-animal methods, can contribute to more predictive, human-relevant and efficient evidence generation in biotechnology, particularly in the area of health. Their use should not lower applicable standards of safety, quality, efficacy, ethics, environmental protection or scientific scrutiny.

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

⁵ Consolidated text: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). ELI:

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

⁵ Consolidated text: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). ELI:

Or. en

Amendment 3

Proposal for a regulation Recital 57

Text proposed by the Commission

(57) Medicinal products developed with innovative biotechnology technologies which will bring a therapeutic advantage to patients should be incentivised with an extension of the Supplementary Protection Certificate.

Amendment

deleted

Or. en

Amendment 4

Proposal for a regulation Recital 113

Text proposed by the Commission

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

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, ***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,

Regulation (EC) No 178/2002 should therefore be amended accordingly.

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 5

Proposal for a regulation Recital 114

Text proposed by the Commission

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

Amendment

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protection of human and animal health and of the environment.

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 6

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 a 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 7

Proposal for a regulation Recital 115

Text proposed by the Commission

(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 Council⁴⁸, it is appropriate to exclude novel foods from the scope of regulatory sandboxes.*** For GMOs legal pathways exist to allow testing of innovations, such as under Part B of Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMOs) for purposes other than placing on the market, and there should not be a duplication of paths in order to maintain legal certainty. For this reason, regulatory sandboxes should be restricted to products containing or consisting of GMOs subject to authorisation under Part C of Directive 2001/18/EC. As regards innovations concerning novel plastic recycling technologies for plastics intended to come into contact with food, chapter IV of Commission Regulation (EU) 2022/1616⁴⁹ already establishes a framework that is meant to encourage the development of such novel technologies without prior authorisation. To ensure uniform rules on the development of novel recycling technologies that safeguard the health of the consumers, it is appropriate to exclude the development of recycling technologies from the possible use of regulatory sandboxes and rely instead on the procedure established in chapter IV of Regulation (EU) 2022/1616.

Amendment

(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 regulatory sandboxes should not lower applicable safety, authorisation, labelling, traceability, consumer information or risk assessment 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) 2022/1616⁴⁹ already establishes a framework that is

meant to encourage the development of such novel technologies without prior authorisation. To ensure uniform rules on the development of novel recycling technologies that safeguard the health of the consumers, it is appropriate to exclude the development of recycling technologies from the possible use of regulatory sandboxes and rely instead on the procedure established in chapter IV of Regulation (EU) 2022/1616.

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 8

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 9

Proposal for a regulation Recital 119

Text proposed by the Commission

(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

Amendment

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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.

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 **reasoned 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 10

Proposal for a regulation Recital 161

Text proposed by the Commission

(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.

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. ***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 11

Proposal for a regulation Recital 166

Text proposed by the Commission

(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.

Amendment

deleted

Or. en

Amendment 12

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 13

Proposal for a regulation Article 1 – paragraph 1

Text proposed by the Commission

1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

Amendment

1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity. ***This Regulation shall also contribute, in line with the 'One Health' approach, to addressing risks linked to zoonotic diseases, antimicrobial resistance,***

biological threats, food and feed safety, animal health, animal welfare and ecosystem health through integrated research, surveillance, preparedness and innovation capacities across sectors.

Or. en

Amendment 14

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(aa) the development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies (NAMs), where scientifically appropriate, in order to support human-relevant evidence generation and contribute to the replacement, reduction and refinement of animal testing and use in clinical trials;

Or. en

Amendment 15

Proposal for a regulation

Article 2 – paragraph 1 – point 6

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 16

Proposal for a regulation

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 17

Proposal for a regulation

Article 3 – paragraph 1 – point d – point ii

Text proposed by the Commission

Amendment

(ii) establishing public-private partnerships between universities, vocational education and training providers, businesses, in particular SMEs, start-ups and scale-ups, social partners and applied research institutes;

(ii) establishing public-private partnerships between universities, vocational education and training providers, **trade unions**, businesses, in particular SMEs, start-ups and scale-ups, social partners and applied research institutes **both for human and animal health**;

Or. en

Amendment 18

Proposal for a regulation

Article 3 – paragraph 1 – point e

Text proposed by the Commission

Amendment

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

(e) contributing to strengthening the EU’s preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures **like human and veterinary vaccines against transboundary**

animal diseases and other animal diseases, including zoonotic diseases, where vaccination contributes to the prevention and control of disease and to the reduction of antimicrobial use in animal production.

Or. en

Amendment 19

Proposal for a regulation

Article 22 – paragraph 4 – point b a (new)

Text proposed by the Commission

Amendment

(ba) provide support and finance for biosimilar manufacturing projects and human and veterinary vaccines against zoonotic and emerging infectious diseases for which no licensed vaccine is authorised in the Union, with priority given to applicants demonstrating an established Union biologics manufacturing footprint;

Or. en

Amendment 20

Proposal for a regulation

Chapter IV

Text proposed by the Commission

Amendment

Chapter IV

deleted

EXTENSION OF THE SUPPLEMENTARY PROTECTION CERTIFICATE

Article 27

Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines developed

in the Union

1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council⁶⁹, or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

- (a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;*
- (b) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;*
- (c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;*
- (d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.*

2. The European Medicines Agency ('the Agency') shall assess compliance

with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.

3. Where compliance is confirmed, the Agency shall issue a statement to that effect.

4. A copy of the statement referred to in paragraph 3 of this Article shall be included in the application for a certificate lodged under article 7 of Regulation (EC) No 469/2009.

⁶⁹ Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Justification

Aligned with deletion in animal health.

Amendment 21

Proposal for a regulation

Article 40 – paragraph 3 – introductory part

Text proposed by the Commission

3. Developers **wishing** to participate in a regulatory sandbox referred to in paragraph 1 shall submit a substantiated application to the Commission. That application shall include the following:

Amendment

3. Developers **requesting** to participate in a regulatory sandbox referred to in paragraph 1 shall submit a substantiated application to the Commission. That application shall include the following:

Or. en

Amendment 22

Proposal for a regulation

Article 56 – paragraph 1 – point 1

Regulation (EC) No 178/2002

Article 3 – point 19

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 23

Proposal for a regulation

Article 56 – paragraph 1 – point 1

Regulation (EC) No 178/2002

Article 3 – point 20

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 24

Proposal for a regulation

Article 56 – paragraph 1 – point 3 – point c

Regulation (EC) No 178/2002
Article 28 – paragraph 9 – point h

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 25

Proposal for a regulation

Article 56 – paragraph 1 – point 4

Regulation (EC) No 178/2002

Article 32a – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

To preserve the integrity of the work and activities of the Authority, as a general rule, the staff of the Authority providing the advice shall not be involved in any preparatory scientific or technical work that is directly or indirectly relevant to the application or notification that is the subject of the advice. In situations where specific expertise is required and can be provided only by the same staff, which would normally disqualify or limit their involvement, it may still be possible to allow those individuals to provide observations before a scientific assessment is finalised, while excluding them from direct involvement in discussions or decision-making.

Or. en

Amendment 26

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

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

Text proposed by the Commission

Regulatory sandboxes may be established in relation to the following:

Amendment

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

Or. en

Amendment 27

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

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

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 28

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49a – paragraph 2 – subparagraph 2

Text proposed by the Commission

The making available of products within a regulatory sandbox shall not be regarded as

Amendment

The making available of products within a regulatory sandbox shall not be regarded as

placing on the market.

placing on the market. *Where appropriate, the Commission or the Authority shall also recommend measures in order to mitigate any possible distortion of market conditions as a result of establishing a regulatory sandbox.*

Or. en

Amendment 29

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49a – paragraph 10

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 30

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49a a (new)

Text proposed by the Commission

Amendment

Article 49aa

Recommendation for the establishment of regulatory sandboxes at Union level

1. The Authority may, on its own initiative or upon request by the Commission or one or more Member

States, issue a scientific recommendation to the Commission for the establishment of a regulatory sandbox where pathways for controlled testing, notification or authorisation are not available or appropriate, encompassing:

- (a) all stages of the production, processing and distribution of food, and also of the feed produced for, or fed to food-producing animals;*
- (b) food contact materials, with the exception of plastic recycled materials;*
- (c) products, other than food and feed, containing or consisting of genetically modified organisms as defined in Article 2, point (2), of Directive 2001/18/EC. .*

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

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

- (a) the objectives of the regulatory sandbox;*
- (b) a description of the specific areas that the regulatory sandbox will cover, including the products or substances, processes, technologies and practices;*
- (c) a clearly defined geographical scope;*
- (d) a clearly defined and limited temporal scope;*
- (e) the regulatory or scientific justifications for setting up the regulatory sandbox including a justification as to why the pathways for controlled testing,*

notification or authorisation are not available or appropriate;

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

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

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

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

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

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

3. On the basis of the recommendation of the Authority, the Commission may, by means of implementing acts, establish a regulatory sandbox at Union level or authorise the coordinated establishment of a multinational regulatory sandbox by participating Member States. Prior to adopting an implementing act pursuant to this paragraph, the Commission shall consult the Member States taking into account the recommendation of the Authority and the sandbox plan pursuant to paragraphs 1 and 2 of this Article. Those implementing acts shall be adopted

in accordance with the examination procedure referred to in Article 58(2) of this Regulation.

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

5. The Commission may adopt implementing acts laying down detailed rules for the operation, supervision, monitoring, suspension and termination of regulatory sandboxes established pursuant to this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 58(2) of this Regulation.

Or. en

Amendment 31

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49b – title

Text proposed by the Commission

Establishment of regulatory sandboxes

Amendment

Establishment of regulatory sandboxes **by Member States**

Or. en

Amendment 32

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49b – paragraph 1 – point e

Text proposed by the Commission

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

Amendment

(e) the regulatory or scientific justifications for setting up the regulatory sandbox, ***including a justification as to why the pathways for controlled testing, notification or authorisation are not available or appropriate***;

Or. en

Amendment 33

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49b – paragraph 1 – point h

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 34

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49b – paragraph 1 – point i

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 35

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49b – paragraph 1 – point j

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 36

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Amendments to Regulation (EC) No 178/2002

Article 49b – paragraph 1 – point k

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 37

Proposal for a regulation

Article 56 – paragraph 1 – point 7

Regulation (EC) No 178/2002

Article 49b – paragraph 3

Text proposed by the Commission

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

Amendment

3. Member States shall engage with relevant stakeholders, ***including civil society representatives, trade unions and non-governmental organisations*** during the preparation of a draft regulatory sandbox plan to gather diverse perspectives and foster collaboration.

Or. en

Amendment 38

Proposal for a regulation

Article 57 – paragraph 1 – point 2

Regulation (EC) No 1394/2007

Article 4a – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 39

Proposal for a regulation

Article 57 – paragraph 1 – point 2

Regulation (EC) No 1394/2007

Article 4a – paragraph 1 – point d

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 40

Proposal for a regulation

Article 57 – paragraph 1 – point 2

Regulation (EC) No 1394/2007

Article 4a – paragraph 2

Text proposed by the Commission

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

Amendment

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

Amendment 41

Proposal for a regulation

Article 58 – paragraph 1 – point 1 – point f

Regulation (EU) No 536/2014

Article 2 – point 47 a (new)

Text proposed by the Commission

Amendment

(47a) 'One Health' means One Health as defined in Article 3, point (7), of Regulation (EU) 2022/2371 of the European Parliament and of the Council;

Or. en

Amendment 42

Proposal for a regulation

Article 59 – paragraph 1 – point 2

Regulation (EU) 2019/6

Article 4 – point 47 a (new)

Text proposed by the Commission

Amendment

(47a) 'One Health' means One Health as defined in Article 3, point (7), of Regulation (EU) 2022/2371 of the European Parliament and of the Council;

Or. en

Amendment 43

Proposal for a regulation

Article 59 – paragraph 1 – point 6

Regulation (EU) No 2019/6

Article 40a

(6) The following Article 40a is inserted: **deleted**

‘Article 40a

Extension of the supplementary protection certificate concerning biotechnology medicinal products treating zoonoses developed and authorised in the Union

1. Where a marketing authorisation is granted by the Union to a veterinary medicinal product developed by means of a biotechnology process referred to in paragraphs 2(a) of Article 42 of Regulation (EU) 2019/6 that is intended to diagnose, treat or prevent zoonotic diseases, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009⁷⁴ of the European Parliament and of the Council , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs 1 and 2 of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;

(b) the veterinary medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which at least equivalent to that that of any authorised veterinary medicinal product in the Union for the same zoonotic disease; and

(c) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.

2. *The Agency shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.*

3. *Where compliance is confirmed, the Agency's opinion shall issue a statement to that effect.*

4. *A copy of the statement referred to in paragraph 3 shall be included in the application for a certificate lodged under article 7 of of Regulation (EC) No 469/2009.*

⁷⁴ *Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1'*

Or. en

Amendment 44

Proposal for a regulation

Article 59 – paragraph 1 – point 8

Regulation (EU) 2019/6

Article 136a – paragraph 1 – point a

Text proposed by the Commission

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

Amendment

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

Or. en

ANNEX: DECLARATION OF INPUT

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

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

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

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

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