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NOTE

From:	Presidency
To:	Delegations
No. prev. doc.:	6916/26
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing the European Competitiveness Fund ('ECF'), including the specific programme for defence research and innovation activities, repealing Regulations (EU) 2021/522, (EU) 2021/694, (EU) 2021/697, (EU) 2021/783, and amending Regulations (EU) 2021/696, (EU) 2023/588, (EU) [EDIP] *- Revised Presidency text on Chapter V (Health, biotechnology, agriculture and bioeconomy)*

Delegations will find below a revised Presidency text on Chapter V (Health, biotechnology, agriculture and bioeconomy) with a view to the meeting of the Ad hoc Working Party on the Multiannual Financial Framework (European Competitiveness Fund) on 30 April 2026.

Changes in comparison to the previous Presidency text (document 6916/26) are marked in **bold** for additions and in ~~strikethrough~~ for deletions.

The numbering of the Commission proposal remains unchanged until the end of the negotiations.

General scrutiny reservation: All delegations.

PUBLIC

2025/0555 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on establishing the European Competitiveness Fund ('ECF'), including the specific programme for defence research and innovation activities, repealing Regulations (EU) 2021/522, (EU) 2021/694, (EU) 2021/697, (EU) 2021/783, and amending Regulations (EU) 2021/696, (EU) 2023/588, (EU) [EDIP]

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(31a) **To enhance the Union's competitiveness, resilience and long-term prosperity, it is necessary to promote an integrated approach that recognises the interdependence between the health of people, animals, plants and ecosystems. The One Health approach, as defined by the One Health High Level Expert Panel (OHHLEP), in 2021, provides an integrated and unifying framework that aims to sustainably balance and optimise the health of people, animals, plants and ecosystems and to address threats to public health, food systems, biodiversity and the environment, improving prevention, preparedness and resilience, sustainability and innovation across all relevant sectors. This approach and the possible mobilisation of, and across, related disciplines and levels of governance, will ensure coherent policy responses and enable the Union to safeguard health security, the resilience of health systems, tackle climate change, protect natural resources and biodiversity, safeguard food security, and reinforce the functioning of the Single Market.**

(32) To improve public health and strengthen the competitiveness of the Union, it is crucial to tackle the rise and reduce the burden of communicable and non-communicable diseases through targeted health promotion and disease prevention strategies and continued investments into health systems **and the pharmaceutical and medical devices sectors. In line with the objectives of the European**~~. Following a one~~ Health ~~Approach~~**Union** and building up on impactful actions implemented under Regulation (EU) 2021/522, such ~~action~~**actions**, coupled with capacity-building, the exchange of best practices**, actions towards reducing inequalities in health** and fostering effective, accessible, and resilient

health systems, can significantly boost workforce productivity by improving population health and alleviating labour shortages, while also supporting health systems that drive innovation. Leveraging health data is essential in those efforts, enabling informed decision-making. Moreover, investments into the health sector**, including strategic projects identified in Union legislation,** and fostering innovation **that reflects Union values** by solidifying and streamlining the evidence-based path from medical breakthroughs to marketable solutions is key to enhancing Union competitiveness and also beneficial to reinforcing supply security.

(32a) **The 2021-2027 EU4Health programme has made significant contributions in key areas such as health crisis preparedness and response, health promotion and disease prevention, cancer and rare diseases. To build on the progress made in these areas, the range of actions previously supported under EU4Health and not covered by other programmes of the MFF, should also be considered under the ECF. In particular, for the prevention of, preparedness for, and response to threats that may lead to health emergencies, relevant actions previously supported under EU4Health would continue to be considered under the ECF when they fall within the scope of this Regulation's specific objectives. These actions would complement actions of a more operational nature for health-emergency prevention, preparedness and response carried out under Regulation (EU) [Union Civil Protection Mechanism and Union support for health emergency preparedness and response], which may include activities such as surveillance, rapid deployment of public health measures, reserve capacities, stockpiling and deployment of medical countermeasures, and training and exercises.**

(32b) Biotechnology is one of the most promising technologies of this century with the capacity to revolutionise many areas of the economy, including ~~through~~ health ~~("red" biotechnology)~~, agri-food**, industry, environment** ~~("green" biotechnology), industrial and environmental ("white" biotechnology), and~~ marine ~~biotechnology ("blue" biotechnology)~~**and aquatic sectors**. Strengthening emerging value chains and providing access to **funding,** finance and tailored support for ~~clinical institutions~~**, where relevant, healthcare providers, relevant research performing organisations**, SMEs, startups, scaleups, spin-offs**,** and innovators is essential to ensure that biotechnology delivers solutions **that reflect Union values and** that contributes to the resilience, sustainability and competitiveness of the Union.

(32c) **Agriculture is a strategic sector, which forms the basis for the production of feed and the production and processing of food. It is fundamental to the Union's food sovereignty, competitiveness and to its economic resilience. The sector faces increasing pressures from climate change, water scarcity, floods and biodiversity loss, which have to be addressed to safeguard its competitiveness and the Union's long-term prosperity. Providing agriculture and food producers with the capacity and concrete solutions to transition to a sustainable, climate-neutral, climate-resilient, water-smart agricultural sector, is crucial. This contributes to long-term water quality and security for food and feed production, sustainable use of natural resources and to safeguarding biodiversity. Overall, there is a need to foster the competitiveness, sustainability, resilience and fairness of the agricultural, fisheries, aquaculture, and forestry sectors, as well as rural and coastal areas, ensuring the long-term food security of the Union and safeguarding animal health and plant health.**

(33) The bioeconomy is a growth engine that allows Europe to make a success of the green transition, strengthen its competitiveness and strategic autonomy. Although Europe's bioeconomy is already reshaping industrial ecosystems, reinforcing strategic autonomy, and unlocking value across strategic sectors, it is crucial to strengthen investments, initiatives, and strategies at Union and Member State level to move it from niche to norm across Union sectors and regions, in order to fully realise its potential, particularly for key industries. ~~There is a need to foster the competitiveness, sustainability, resilience and fairness of the agricultural, fisheries, aquaculture and forestry sectors, of rural and coastal areas and to contribute to long-term food security in the Union.~~

(34) Investments, initiatives and strategies are needed to close the innovation gap and accelerate the discovery, development, derisking, demonstration, scaleup **and manufacturing** of bioeconomy innovations, to support their market uptake, to provide finance along the innovation journey for startups and for scaling up high growth companies, to maximise resource efficiency and to secure sustainably sourced biomass supply. The bioeconomy contributes to decarbonisation, by providing sustainable alternatives to fossil-based products and processes, but also to circularity, the clean transition, carbon farming, biodiversity, ecosystem services, and nature restoration.

Chapter I

General Provisions

SECTION 1

OBJECTIVES AND STRUCTURE OF THE FUND

PUBLIC

Article 3

Objectives

2. Under the general objectives set out in paragraph 1, the ECF shall in particular pursue the following specific objectives:

(b) For support to Health, Biotechnology, Agriculture and Bioeconomy:

(i) For support to health, the specific objectives of fostering innovation and competitiveness of the health sector for the benefit of people and society across the Union while ensuring ~~the~~ translation of innovation into practice, supply security and the industrial capacity and capability **required** to manage public health challenges and future serious cross-border threats to health; improving and protecting public and population health, by prioritising health promotion and disease prevention **and by developing better diagnosis and treatment** across the life span through health-in-all and One Health policies, and by strengthening the innovation**, preparedness, sustainability** and resilience of health systems **and public health authorities**.

(ii) For support to biotechnology, the specific objectives of contributing to ~~the~~**innovation,** development and scalable production and uptake, availability and accessibility of biotechnological solutions**, including medicinal products, medical devices, in vitro diagnostic medical devices and medical countermeasures**.

(iii) For support to bioeconomy policy, the specific objectives of fostering an innovative and competitive bioeconomy in the Union, including in the areas of biobased materials and products, biomanufacturing, innovative food products**,** and bio-based chemicals; including support to SMEs, start ups and scaleups, advancing the development and scalable production and uptake, availability and accessibility of bioeconomy innovations, including those based on cross-sectoral cutting-edge biotechnology and bio-based solutions, strengthen supply chains and increase their resilience.

(iv) For support to agriculture and food security, the specific objective of fostering the competitiveness, innovation, sustainability, and resilience of agriculture ~~and~~**,** food systems, fisheries ~~and~~**,** aquaculture, forestry,~~ and~~ rural and coastal areas and their role in mitigating the climate, environmental and biodiversity crises**, as well as in safeguarding animal health and plant health**.

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CHAPTER V

SUPPORT FOR HEALTH, ~~BIOTECH~~BIOTECHNOLOGY, AGRICULTURE AND BIOECONOMY

PUBLIC

Article 36

Specific provisions for support to health, ~~biotech~~biotechnology, agriculture and bioeconomy policies

1. Actions supported under this chapter shall contribute to the general objectives set out in Article 3(1) and the specific objectives set out in Article 3(2), point (b).

2. Support for actions under this chapter shall be financed from the budget set out in Article 4(2), point (c), and any additional contributions assigned in accordance with Article 5.

Article 37

Specific Activities

1. Support for Health, ~~Biotech~~**Biotechnology**, Agriculture and Bioeconomy policy shall be implemented in particular through the following activities:

(a) Improving and protecting health, including cross-border health, by prioritising health promotion and disease prevention across the life course, by **fostering early detection and treatment, by** strengthening innovation**,** and through health-in-all and One Health policies~~,~~ with a special emphasis on communicable and non-communicable diseases, including mental health, neurodegenerative diseases, cardiovascular diseases, rare diseases, cancer and other diseases, including those related to pollution and climate change, antimicrobial resistance (AMR), sexual and reproductive health~~,~~ and enhancing global health initiatives and cooperation.

(b) Strengthening the efficiency**, accessibility, sustainability**, innovation and resilience of health systems by reinforcing access to, sharing, use and re-use of health data and digital tools, infrastructures and services, including to support the European Health Data Space, deployment of Artificial Intelligence and digital or robotics based solutions **and other innovative approaches** in healthcare, advancing the digital

transformation of healthcare, enhancing equitable access to and quality of **patient-centred, outcome-based** healthcare services, with particular focus on public health and healthcare workforce, promoting evidence-based decision-making, (including by supporting Health Technology Assessment), supporting clinical trials, including multi country clinical trials, **and integrating the work of the European Reference Networks (ERNs),** providing digital solutions for monitoring, coordinating and encouraging exchange of best practices, capacity building**,** ~~and~~ integrated work among national health systems**, including, where appropriate, actions and networks between competent health authorities,** to ensure coherence and efficiency across the Union.

(c) Fostering ~~the~~ development, production capacity, manufacturing and industrial deployment of health technologies, to increase the competitiveness of the sector, including through the development of advanced therapies such as ATMPs (Advanced Therapy Medicinal Product)**, including among others through strategic projects identified in Union legislation** and ensure availability of Union medicinal products, medical devices, in vitro diagnostic medical devices, critical medicinal products, digital solutions and medical countermeasures relevant for preparedness and response to cross-border threats to health, as well as the competitiveness and resilience of the sectors by ensuring that such products are innovative, safe, accessible, available, and affordable, thereby promoting equitable access across the Union.

(e) Protecting people by supporting the development, implementation and monitoring of health security policies **to combat serious cross-border threats to health**, in cooperation with Member States authorities and stakeholders, as well as coordinating Union, national prevention, preparedness and response plans.

(ea) Supporting the discovery, development, derisking, demonstration, piloting and use, and scale-up of biotechnology innovations, accelerating the market introduction and market uptake of biotechnology solutions, strengthening emerging value chains and providing access to finance and other support **including among others** for SMEs, startups**, research performing organisations, healthcare providers**, scale-ups, skilled workforce and innovators.

(f) Fostering an innovative, sustainable and competitive bioeconomy sector in the Union, including in the areas of health, biotechnology, bio-based materials and products, valorising farm and forest residues and food waste, carbon negative products, biomanufacturing and bio-based chemicals, in particular by supporting the discovery, development, derisking, demonstration, piloting, **manufacturing** and scaling-up of bioeconomy innovations; by accelerating the market introduction and market uptake of bio-based materials from agriculture and forestry**, taking into account the role of** ~~and~~ other ~~primary production, and~~**sectors such as fisheries and aquaculture, and by accelerating** bioeconomy solutions; by strengthening emerging value chains; by building a skilled workforce, by providing access to finance and other support for SMEs, startups, ~~scale ups~~**scale-ups** and innovators.

(g) Fostering the competitiveness, the sustainability, the resilience and fairness of ~~the~~ agriculture ~~and~~**,** food systems, fisheries, aquaculture, forestry ~~sectors~~**,** and rural and coastal areas~~, and~~**. This includes** their role in the transition to a climate-neutral, climate-resilient, water-smart, nature-positive economy and the protection of **biodiversity and** natural resources ~~and biodiversity, while~~**, in** contributing to **the long-term water quality and security for food production, and to the** long-term food security in the Union**, as well as in safeguarding animal health and plant health**.

(h) Supporting actions for the development, implementation, monitoring and enforcement of relevant Union legislation and policy. This includes supporting the relevant institutions, the cooperation between national authorities and with stakeholders, studies, the development and deployment of tools and infrastructures, including IT infrastructure and tools.

2. Work programmes adopted in accordance with the rules of this Regulation under this chapter shall integrate in a specific dedicated part and ensure coherence with [Competitiveness and Society activities supported under the Regulation (EU) [XXX] [Horizon Europe Framework programme for Research and Innovation.