



Paris, 4 April 2025

POLITICAL OPINION

to promote fundamental research and breakthrough innovation in the field of extracellular RNA and extracellular vesicles

- (1) The Senate European Affairs Committee,
- (2) Having regard to the Treaty on the Functioning of the European Union, in particular Articles 168, 179 and 180,
- (3) Having regard to Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe - the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013,
- (4) Having regard to Council Decision (EU) 2021/764 of 10 May 2021 establishing the specific programme implementing Horizon Europe - the Framework Programme for Research and Innovation, and repealing Decision 2013/743/EU,
- (5) Having regard to Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241,
- (6) Having regard to Regulation (EU) 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,

- (7) Having regard to Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU,
- (8) Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC,
- (9) Having regard to the Communication from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 20 March 2024 and entitled "Building the future with nature: Boosting Biotechnology and Biomanufacturing in the European Union", COM(2024) 137 final,
- (10) Having regard to the report of the European Commission expert group on the interim evaluation of the Horizon Europe programme of 16 October 2024 entitled "Align, Act, Accelerate: research, technology and innovation to boost European competitiveness",
- (11) Having regard to the report by Mr Enrico Letta dated 18 April 2024 and entitled "Much more than a market - Speed, security, solidarity - Empowering the Single Market to deliver a sustainable future and prosperity for all EU citizens",
- (12) Having regard to the report by Mr Mario Draghi dated 9 September 2024 and entitled "The Future of European Competitiveness",
- (13) Having regard to the report by the OECD Environment Directorate dated 30 August 2023 and entitled "Considerations for the Human Health Risk Assessment of Externally-Applied dsRNA-Based Pesticides", ENV/CBC/MONO(2023) 26,
- (14) Having regard to the report by the OECD Environment Directorate dated 17 March 2023 and entitled "Considerations for the Environmental Risk Assessment of the Application of Sprayed or Externally Applied dsRNA-Based Pesticides", ENV/JM/MONO(2020) 23,
- (15) Whereas recent progress has been made by European scientific research into extracellular ribonucleic acids (exRNA) and extracellular vesicles (EVs);
- (16) Whereas there are potential applications for human, animal and plant health, as well as for agriculture;
- (17) Whereas opportunities are offered by scientific and academic cooperation at European level;
- (18) Whereas biotechnologies, including those based on the properties of exRNA and EVs, are considered, under the terms of Regulation (EU) 2024/795

referred to above, as likely to contribute to reducing or preventing the Union's strategic dependencies;

- (19) Recognises that technologies based on the properties of exRNA and EVs can contribute to strengthening the European Union's strategic autonomy, particularly in the fields of health and agriculture;
- (20) Considers that research and development in this field should be supported accordingly;
- (21) *In financial terms*
- (22) Whereas the Horizon Europe Framework Programme provides funding for research and innovation within the European Union;
- (23) Whereas the funds of the Horizon Europe Framework Programme are allocated through calls for projects drawn up on the basis of work programmes proposed by the European Commission;
- (24) Whereas these calls for projects are intended to meet certain objectives and the technology used is often left to the discretion of the project promoters;
- (25) Whereas a breakthrough innovation is a technological innovation involving a product or service that eventually replaces a dominant technology on a market;
- (26) Whereas certain technologies developed thanks to the properties of exRNA and extracellular vesicles may constitute breakthrough innovations;
- (27) Whereas there are difficulties associated with the scaling up of biotechnology companies within the European Union, scaling up being defined as the transition from the development stage of a product to the marketing stage;
- (28) Whereas these difficulties are greater in the case of disruptive innovations;
- (29) Whereas the European Union risks falling behind the United States and China in scientific and industrial terms, and needs to position itself in breakthrough technologies in order to benefit from the industrial return on scientific investment, most of which is made with public funds;
- (30) Requests that the work programmes of the Horizon Europe Framework Programme provide specific support for innovations based on the properties of exRNA and extracellular vesicles, particularly when these are breakthrough innovations;
- (31) Recalls the need to simplify the administrative procedures required to obtain funding under the Horizon Europe Framework Programme, particularly for small and medium-sized enterprises;
- (32) Considers it essential to mobilise private investment to finance the development of innovative businesses and their scaling up, in particular

through the development of suitable long-term savings products and the establishment of a savings and investments union;

(33) *In regulatory terms*

(34) Whereas extracellular vesicles are defined as biological products, although the process for their manufacture is more similar to that of gene therapy products;

(35) Whereas the criteria for controlling the quality of extracellular vesicles produced on a large scale have not yet been fully defined;

(36) Whereas the Commission wishes to propose a regulation in 2026 to stimulate the development of biotechnology by emphasising the need for a new regulatory environment that is conducive to innovation, particularly in the areas of health technology assessment and clinical trials;

(37) Whereas technologies based on the properties of exRNA and extracellular vesicles are innovative in nature and may entail difficulties in determining the legislation applicable to a given technology;

(38) Whereas companies have expressed a need for advice in implementing the regulatory procedures necessary for the development and marketing of their products;

(39) Whereas there are differences between a plant protection product based on chemical molecules and a plant protection product based on RNA;

(40) Encourages the creation of specific platforms with the appropriate authorisations to produce extracellular vesicles, and the definition of guidelines for quality control of production;

(41) Calls for the possibilities for companies to benefit from regulatory advice from the competent authorities of the Union and the Member States to be developed;

(42) Supports in principle the idea of a European regulation aimed at stimulating the development of biotechnologies within the Union; stresses that this will have to be the subject of broad consultation and take account of the conclusions of the various studies launched by the European Commission further to its communication of 20 March 2024;

(43) Recommends that an appropriate procedure be established for the evaluation of RNA-based plant protection products;

(44) Points out, however, that measures aimed at simplifying or adapting EU regulations in the field of biotechnology must protect human health and the environment and respect the competences of the Member States.