



**EUROPEAN COMMISSION**  
Directorate-General for Research and Innovation  
**Directorate for Prosperity**

***INFORMAL COMMISSION EXPERT GROUP 'BIOTECHNOLOGIES RISK ASSESSMENT  
UNDER THE EUROPEAN ECONOMIC SECURITY STRATEGY'***

TERMS OF REFERENCE

## **1. BACKGROUND**

The purpose of this Expert Group is to support the implementation of the Economic Security Strategy<sup>1</sup>. The Commission Recommendation of 3 October on critical technologies<sup>2</sup> initiates joint risk assessments with regard to the most sensitive and immediate risks related to technology security and technology leakage for four technologies critical for economic security: advanced semiconductors technologies, artificial intelligence technologies, quantum technologies, and biotechnologies.

The expert group will contribute to the assessment of strengths and weaknesses in national ecosystems for the biotechnologies. In line with the Economic Security Strategy, the group will analyse risks to technology security and technology leakage related to biotechnologies. This includes potential risks of leakage of EU knowledge and technologies that could be used for civil-military fusion or human rights violations.

## **2. SUBJECT MATTER**

The group of experts 'Biotechnologies risk assessment under the European Economic Security strategy' ('the group') is set up. The joint risk assessments will be an iterative process.

## **3. TASKS**

The group's tasks shall be to:

- a) support the European Commission with the delivery of national economic security risk assessments for the subset of biotechnologies: genomic modification/editing (techniques of genetic modification, new genomic techniques, gene-drive), synthetic biology, bioprinting and bioinformatics, as well as potentially other sectors seen as relevant by the expert group.

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<sup>1</sup> [EUR-Lex - 52023JC0020 - EN - EUR-Lex \(europa.eu\)](#)

<sup>2</sup> [Commission Recommendation \(EU\) 2023/2113 of 3 October 2023 on critical technology areas for the EU's economic security for further risk assessment with Member States \(europa.eu\)](#)

- b) identify strengths and weaknesses in national ecosystems in relation to the respective value chains, national assets and capabilities (major players – companies, universities, research organisations, etc.), as well as dependencies on third countries on products, know-how, equipment or any other relevant input for the development and/or use of these biotechnologies.
- c) identify and analyse vulnerabilities according to their potential impact on the EU's economic security and the degree of likelihood that the negative impact materialises.
- d) identify the main types of threats and threat actors, and taking into account geopolitical factors where relevant to assess the likelihood of negative impacts.
- e) take into account, inter alia, the value chain of the technologies, the evolution of risks as well as relevant technological developments, including any chokepoints and expected future chokepoints, a mapping of the EU's relative position in each technology, including key players and elements of the EU's comparative lead; the global interconnectivity of the ecosystem of the technology, including in research and the supply chain for the technology.

#### **4. MEMBERSHIP**

1. Members shall be Member States' competent authorities.
2. Member States' authorities shall nominate their representatives and shall be responsible for ensuring that their representatives provide a high level of expertise.
3. Members who are no longer capable of contributing effectively to the expert group's deliberations, who, in the opinion of DG RTD, do not comply with the conditions set out in Article 339 of the Treaty on the Functioning of the European Union or who resign, shall no longer be invited to participate in any meetings of the group and may be replaced for the remainder of their term of office.

#### **5. CHAIR**

The group shall be chaired by a representative of DG RTD.

#### **6. OPERATION**

1. The group shall act at the request of DG RTD in compliance with the horizontal rules<sup>3</sup>.
2. Meetings of the group shall, in principle, be held on Commission premises or virtually, depending on the circumstances.
3. DG RTD shall provide secretarial services. Commission officials from other departments with an interest in the proceedings may attend meetings of the group and its sub-groups.
4. In agreement with DG RTD, the group may, by simple majority of its members, decide that deliberations shall be public.

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<sup>3</sup> C(2016) 3301, Article 13.1.

5. When discussions in the group deem to be confidential and touch upon sensitive issues, the organisation of meetings, including exchanges of information and documents shall be conducted using adequately secured channels. The Secretariat and the members shall be responsible for ensuring appropriate handling.
6. Minutes on the discussion on each point on the agenda and on the opinions delivered by the group shall be meaningful and complete. Minutes shall be drafted by the secretariat under the responsibility of the Chair.
7. As far as possible, the group shall adopt its opinions, recommendations or reports by consensus. In the event of a vote, the outcome of the vote shall be decided by simple majority of the members. Members who have voted against or abstained shall have the right to have a document summarising the reasons for their position annexed to the opinions, recommendations or reports.

## **7. SUB-GROUPS**

DG RTD may set up sub-groups for the purpose of examining specific questions on the basis of terms of reference defined by DG RTD. Sub-groups shall operate in compliance with the horizontal rules and shall report to the group. They shall be dissolved as soon as their mandate is fulfilled.

## **8. INVITED EXPERTS**

DG RTD may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the group or sub-groups on an *ad hoc* basis.

## **9. RULES OF PROCEDURE**

On a proposal by and in agreement with DG RTD the group shall adopt its rules of procedure by simple majority of its members, on the basis of the standard rules of procedure for expert groups, in compliance with the horizontal rules<sup>4</sup>. Sub-groups shall operate in compliance with the group's rules of procedure.

## **10. PROFESSIONAL SECRECY AND HANDLING OF CLASSIFIED INFORMATION**

The members of the group and their representatives, as well as invited experts, are subject to the obligation of professional secrecy, which by virtue of the Treaties and the rules implementing them applies to all members of the institutions and their staff, as well as to the Commission's rules on security regarding the protection of Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/443<sup>5</sup> and 2015/444<sup>6</sup>. Should they fail to respect these obligations, the Commission may take all appropriate measures.

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<sup>4</sup> See Article 17 of the horizontal rules.

<sup>5</sup> Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

<sup>6</sup> Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

## **11. TRANSPARENCY**

1. The group and sub-groups shall be registered in the Register of Commission expert groups and other similar entities ('the Register of expert groups').
2. As regards the group and sub-groups composition, the name of Member States' authorities shall be published on the Register of expert groups.
3. All relevant documents, including the agendas, the minutes and the participants' submissions, shall be made available on the Register of expert groups. In particular, DG RTD shall publish the agenda and other relevant background documents in due time ahead of the meeting, followed by timely publication of minutes. Exceptions to publication shall only be possible where it is deemed that disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) N° 1049/2001<sup>7</sup>.

## **12. MEETING EXPENSES**

1. Participants in the activities of the group and sub-groups shall not be remunerated for the services they offer.
2. Travel expenses incurred by participants in the activities of the group and sub-groups shall be reimbursed by the Commission. Reimbursement shall be made in accordance with the provisions in force within the Commission and within the limits of the available appropriations allocated to the Commission departments under the annual procedure for the allocation of resources.

Done in Brussels, on 22 March 2024

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<sup>7</sup> These exceptions are intended to protect public security, military affairs, international relations, financial, monetary or economic policy, privacy and integrity of the individual, commercial interests, court proceedings and legal advice, inspections/investigations/audits and the institution's decision-making process.