

KEY POINTS FOR CONSUMERS

Biotech Act I

Why it matters to consumers

Biotechnologies like vaccines, gene-therapies, or alcoholic fermentation in bread to enhance flavours are increasingly shaping Europe's health and food systems, directly affecting patients and consumers. Innovation and competitiveness matter but must never compromise safety or public trust. Simplification must ensure rigorous risk assessment, and respect for the precautionary principle. Transparency and clear safeguards are essential to ensure innovation serves the public interest.

The table assesses the Commission's proposal with the following symbols, illustrating:



what BEUC supports



what can be improved



what BEUC considers problematic

COMMISSION PROPOSAL

BEUC POSITION

HEALTH

PROPOSAL TO AMEND THE CLINICAL TRIALS REGULATION

The Commission proposes shortening authorities' clinical trial assessment timelines, including by automating completion of the initial administrative part past a short deadline. This can accelerate patients' access to trials and innovative treatments.



Authorities need **sufficient resources to protect trial participants** and ensure robust trial design without lowering the quality of scientific and ethical review.

Competent authorities should always validate that clinical trial applications are complete. The proposal to trigger automated completion of the application's administrative part risks misclassifying trials to categories requiring fewer safeguards. It may also compromise patients' safety.

STRATEGIC PROJECTS

Providing targeted support for Strategic Projects can boost EU biotech's development and manufacturing capacity.



To maximise public return on investment, funding needs tying to stronger conditionalities:

- Public funding beneficiaries must adopt measures that contribute to medicines' **availability and affordability**. Beneficiaries should detail these measures in an "access plan" with clear guidelines from the Commission and Member States.
- Reviewing Member States must publish the outcome of each Strategic Project application's assessment and add it to an EU register for transparency.

HEALTH

SUPPLEMENTARY PROTECTION CERTIFICATE ('SPC')

To further incentivise biotech development in the EU, the Commission extends the monopoly over a medicine.



A 12-month SPC extension risks delaying the arrival of cheaper generics biosimilars on the market, undermining the balance between innovation and affordability in the new pharmaceutical law, leading to higher costs for consumers and health systems.

Instead, the EU should focus on public funding mechanisms that support Strategic Projects. The EU and Member States must prioritise **public-health driven push and pull** incentives, such as milestone prizes.

FOOD

EU FOOD SAFETY AUTHORITY (EFSA)'S ADVISING ROLE

The EU should expand EFSA's advising role in food products' nutritional properties, to address rising diet-related diseases.

EFSA's expanded role requires **sufficient, dedicated resources** to protect its core task of independent risk assessment. Transparency and independence safeguards maintain public trust in the system:

- EFSA must keep **its advisory and assessment roles separate**.
- **For transparency**, applicants must disclose how they followed EFSA's advice in their submission and justify where they departed from it. Similarly, the Agency's Scientific Opinion should detail its pre-submission activities.
- EFSA should regularly update its public guidance documents on study, to streamline its use of resources.

PRE-SUBMISSION ADVICE ('PSA') AND SCIENTIFIC ADVICE

Early guidance from EFSA to applicants can improve the quality of their application.



EFSA's core scientific work should receive **financing through stable and sustainable public funding** under the EU budget.

The Commission proposal to rely on company application fees would weaken EFSA's budget predictability, constrain long-term planning, and create dependence on a steady flow of industry applications.

FEES TO FINANCE EFSA**REGULATORY SANDBOXES AND NOVEL FOODS**

A regulatory sandbox allows regulators to let firms test new innovative products under temporary and more flexible rules.



Sandboxes could potentially support innovation in areas where there are scientific challenges, and accelerate market access in urgent cases (e.g., health technologies for serious diseases). **Food does not require this type of flexibility and should remain outside sandboxes** to protect consumers and trust in the EU food system.

Novel foods' testing and validation should therefore stay under existing rules. The current authorisation system, reinforced by EFSA pre-submission and scientific advice, already supports innovation while ensuring high safety standards.