Biotech Act strengthening the biotechnology sector

Published by AGRINFO on 17 May 2026

Proposal for a Regulation on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health […] (European Biotech Act)

Proposal for a regulation: COM(2025)1022 [download]

Proposed Annex: COM(2025)1022 [download]

What is changing and why?

The European Biotech Act I will revise rules across all areas of the biotechnology sector, including agri-food products, with the aim of boosting research and innovation.

The European Commission proposes rule changes that will:

- allow applicants seeking the authorisation or renewal of genetically modified (GM) products to seek pre-submission advice on study design and testing strategies from the European Food Safety Authority (EFSA)
- where applicants have failed to notify supporting studies to EFSA, allow resubmitted applications to be assessed more rapidly by EFSA (within 6 months of notification, rather than 3 months)
- create "regulatory sandboxes", controlled environments within the European Union in which companies can test innovative food products (including GM foods, but not novel foods) at a pre-market stage for a limited period of time.

Actions

The consultation via the European Commission's Have your say platform closed on 5 August 2026.

Timeline

The proposal is expected to be put forward in the second half of 2026 to the European Parliament and Council of the EU (Member States) for discussion and adoption. This process can typically last 2 years.

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