

Biotech Act strengthening the biotechnology sector

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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

All interested stakeholders are invited to give feedback via the European Commission's [Have your say](#) platform until **5 August 2026**.

Stakeholders wishing to respond must be registered. Those who do not already have an account will first need to [Create an EU login account](#), then register their organisation on the EU [Transparency register](#).

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.

For more information see the [full record](#) on the AGRINFO website – where you can also view the latest [AGRINFO Update](#) newsletters and [search](#) the database.

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