Biotech Act strengthening the biotechnology sector

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EU proposes greater support for authorisation of genetically modified agri-food products

Proposal for a Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)

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

Proposed Annex: COM(2025)1022 [download]

Update

The European Biotech Act I will aim to stimulate all areas of the biotechnology sector, including agri-food products, by encouraging research and innovation.

With this Regulation, the European Commission proposes to introduce changes to the General Food Law (Regulation (EC) 178/2002) 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"; these are controlled environments within the EU 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.

There is an opportunity to provide feedback via the Commission's Have your say platform until **5 August 2026**.

Impacted products

Genetically modified (GM) foods

What is changing?

Biotech Act I

The European Biotech Act I covers all biotechnology sectors (human medical, veterinary, pharmaceutical, and food).

The changes that are relevant to agri-food products involve amendments to the General Food Law (Regulation (EC) 178/2002)

General Food Law

The proposed changes include the following.

- Currently, applicants seeking the authorisation or renewal of GM products can seek pre-submission advice from EFSA; the European Commission proposes to extend this to include scientific advice on study design and testing strategies.
- Studies carried out to support an application must be notified in advance to EFSA. Where studies have not been notified, the application must be resubmitted and currently will be assessed by EFSA 6 months after notification. The Commission proposes to reduce that period to 3 months.
- The Commission proposes to create “regulatory sandboxes”, controlled environments within the EU in which companies can test innovative products at a pre-market stage for a limited period of time. However, such sandboxes cannot be used in relation to novel foods.

Biotech Act II

The EU is also preparing a Biotech Act II that aims to boost industrial biotechnology and biomanufacturing within the European Union. However, this has limited relevance to non-EU stakeholders. See Biotech Act II: Call for evidence.

Why?

The acceleration of risk assessment processes, and advice for companies in the authorisation of new products, could potentially support innovation.

The creation of regulatory sandboxes is intended to stimulate food innovation, making products available in a limited way for the purposes of testing and collecting information, while ensuring no risks to consumers.

In particular, these sandboxes are intended to:

- facilitate the development, testing, and validation of technologies, substances, and products prior to authorisation
- test data requirements, including study design
- test alternatives to existing regulatory requirements to ensure they can meet EU objectives.

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.

Recommended 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.

Background

For further information on EU GM food rules, see the European Commission's webpage on GMO legislation.

Resources

Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

European Commission (2025) Commission Staff Working Document accompanying the proposal for a Regulation [download SWD(2025)1055]

Sources

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