



Council of the European Union  
General Secretariat

**Brussels, 22 September 2025**

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#### **WORKING DOCUMENT**

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**From:** General Secretariat of the Council  
**To:** Working Party on Competitiveness and Growth (Industry)

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**Subject:** Presentations by the European Commission : The role of the bioeconomy and biotechnology for industrial competitiveness (agenda item 3)  
Working Party on Competitiveness and Growth (Industry) meeting on 22 September 2025

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# EU Bioeconomy Strategy:

## Public Consultation Results



DG Environment

B Competitive Circular Economy & Clean Industrial Policy

B.1 Circular Economy, Sustainable Production and Consumption

22 September, 2025


# Overall public consultation activities timeline

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# Public consultation activities: target audience and results

- General public
- Businesses and Industries, including SMEs
- Primary producers of biomass, farmers and foresters
- Social partners, representatives of manufacturing & services
- Non-governmental organisations
- Consultancies
- Organisations supporting research, innovation, education
- Organisations representing regional, local, and municipal authorities
- National and regional public authorities, EU decentralised agencies and other bodies (EU agencies), as well as public authorities of non-EU countries, or international organisations



Stakeholders' dialogue	<ul style="list-style-type: none"><li>• 4 Workshops, 1 per pillar on 8-9th July</li><li>• 133 participants</li></ul>
Call for evidence	<ul style="list-style-type: none"><li>• 444 responses received</li><li>• 300 position papers</li></ul>
Public consultation survey	<ul style="list-style-type: none"><li>• 362 replies</li><li>• 149 additional files</li><li>• 31 March until 23 June</li></ul>

*The summary of the Public consultation survey can be found on the [‘Have Your Say’](#) portal*

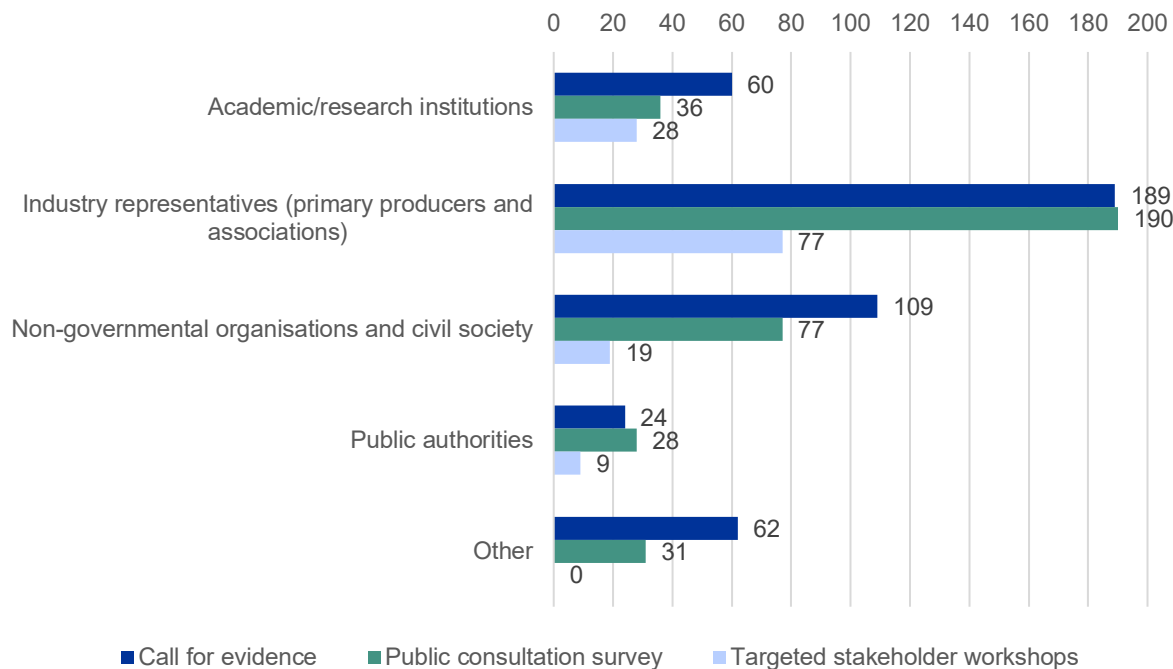


# Stakeholder profile of respondents to the public consultation activities

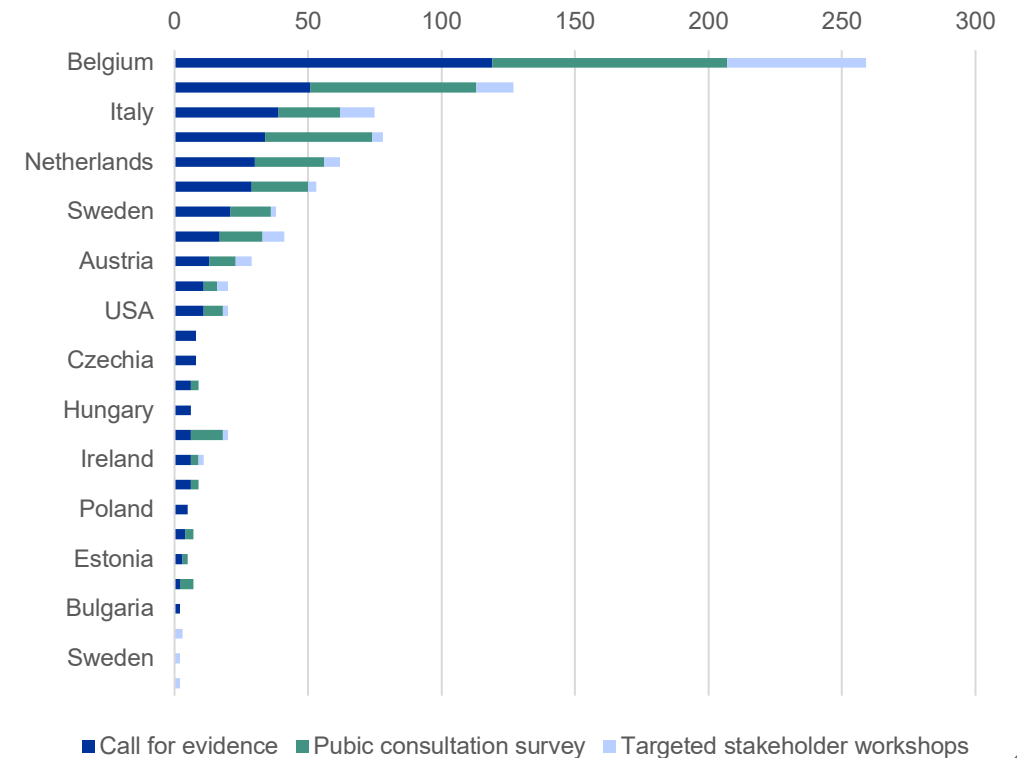
- The largest group of respondents were Industry representatives, followed by NGOs and civil society in call for evidence and public consultation survey. Industry and Academic/research institutions were the major stakeholder groups in the stakeholder workshops.

- Geographically, respondents were primarily from EU countries, with Belgium and Germany leading both the Call for evidence, Public consultation survey and stakeholder workshops.

No of respondents in stakeholder groups by consultation activity



Stakeholder analysis by country (only 2 or more)

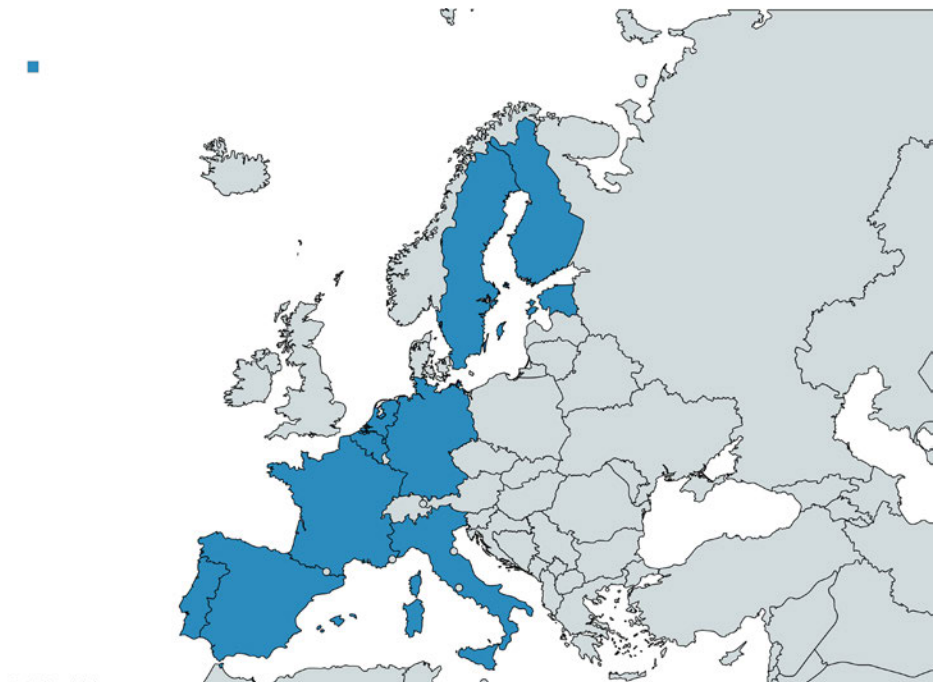
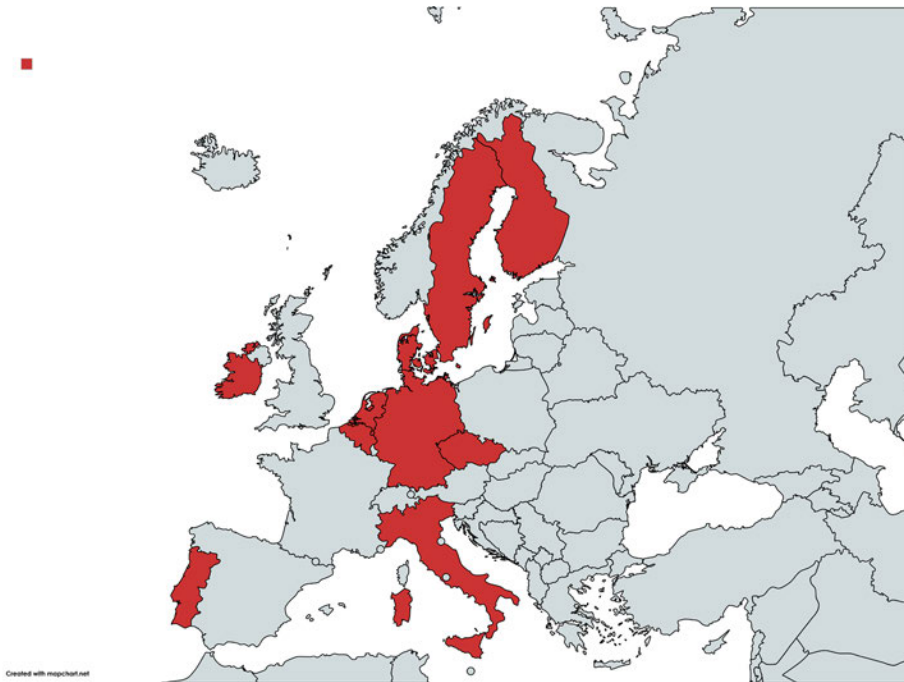


# Public Authorities

The participation of public authorities in the consultation process at EU level includes contributions from 13 Member States.

Of these, 9 MS (in red, below), 25 regions (in blue, below) and Paris city shared dedicated position papers.

At global level, the Australian government was the only public authority that provided a position paper on this area. In terms of supranational organisations, the World Economic Forum, and the UN Food and Agriculture Organization, and the International Organization for Migration have as well contributed to the consultation.



# Methodological approach for consultation activities



Public consultation survey and call for evidence collected stakeholder feedback on drivers and barriers for the new EU Bioeconomy Strategy between 31 March and 23 June 2025.



Four targeted stakeholder workshops gathered stakeholder insights, drivers, barriers and recommendations that will inform the new EU Bioeconomy Strategy.



Step 1



Step 2



Step 3



Step 4

APPROACH

## Data collection

- Call for evidence (444 open text responses, 300 position papers)
- Public consultation survey (362 responses, 149 with 169 position papers)
- Targeted stakeholder workshops – 133 stakeholders.

## Data cleaning and quality assurance

- Remove duplicates
- Campaign detection
- Abusive content screening

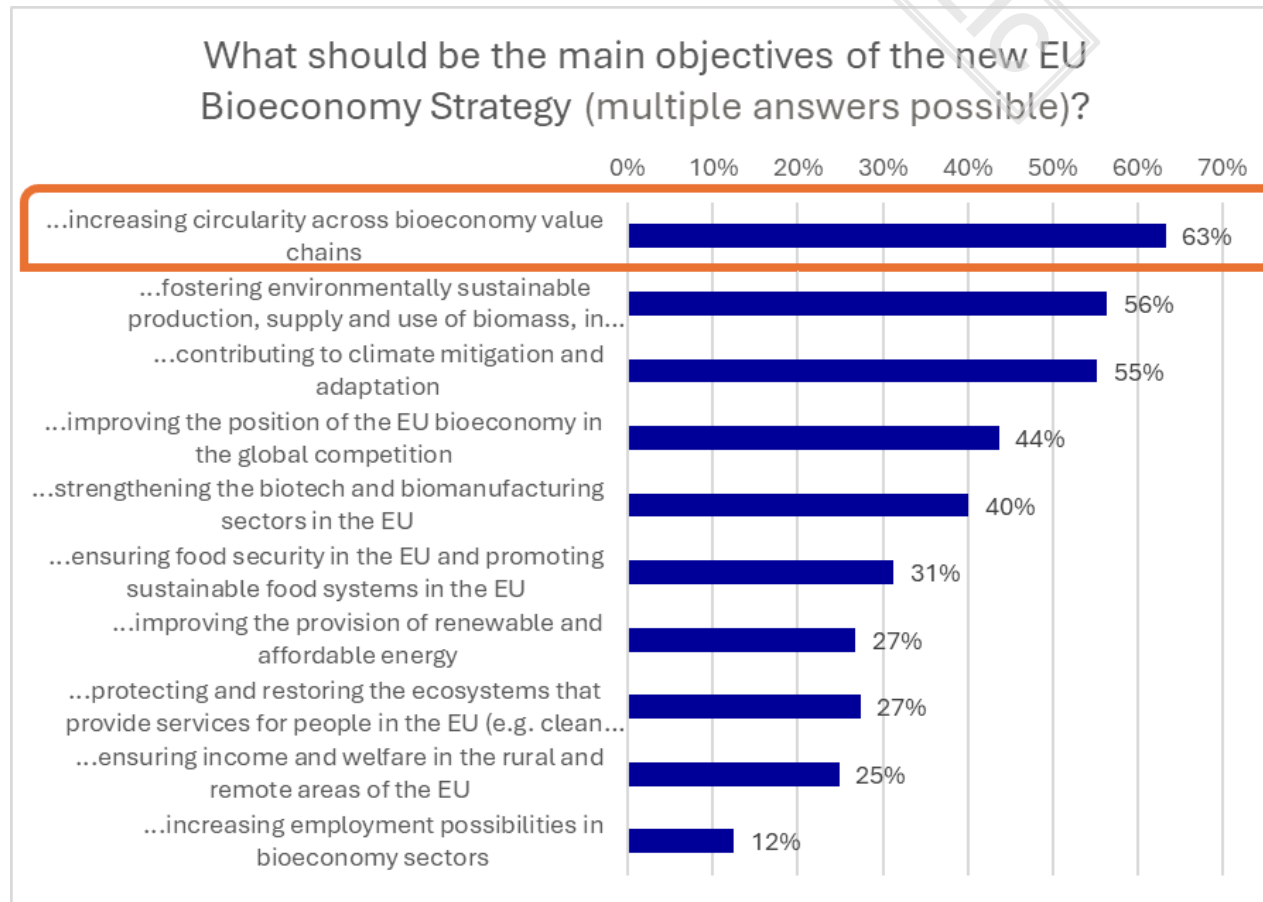
## Quantitative and qualitative analysis

- Structured survey results
- Open text and position papers analysis
- Mapped recommendations and barriers to Bioeconomy Strategy pillars
- Applied the drivers-barriers framework for classification and quantification of results

## Integration and reporting

- Produced a structured overview of key themes, drivers, barriers, and recommendations across stakeholder groups per Bioeconomy Strategy pillars

# Main objectives of the new EU Bioeconomy Strategy identified in the Public consultation survey

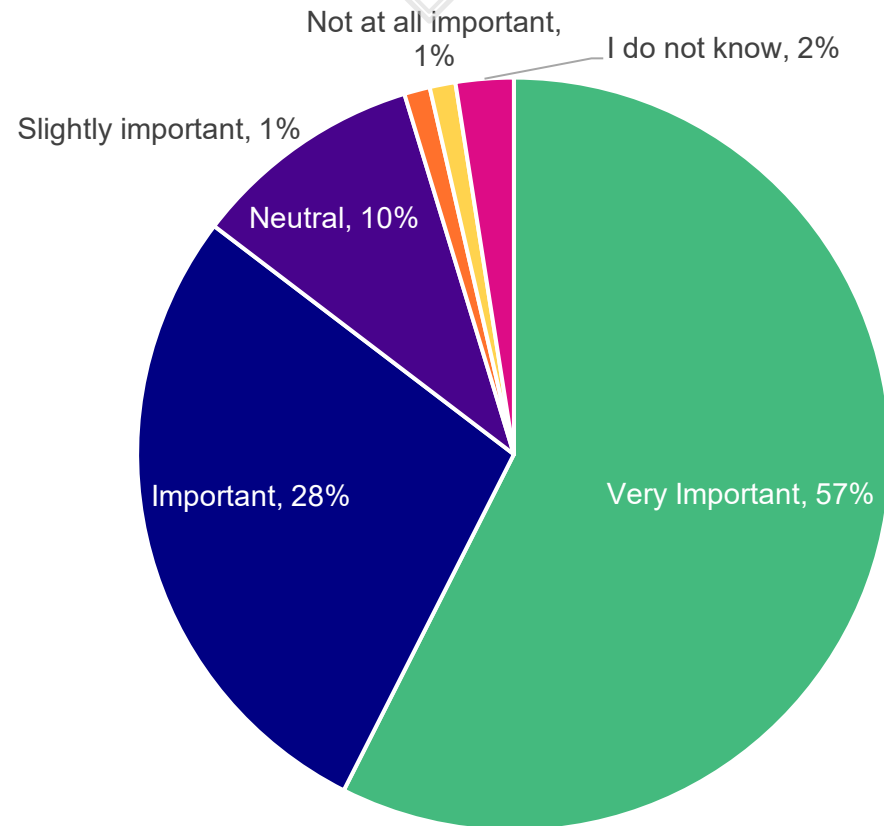


# Challenges and needed regulatory measures identified in the Public consultation survey

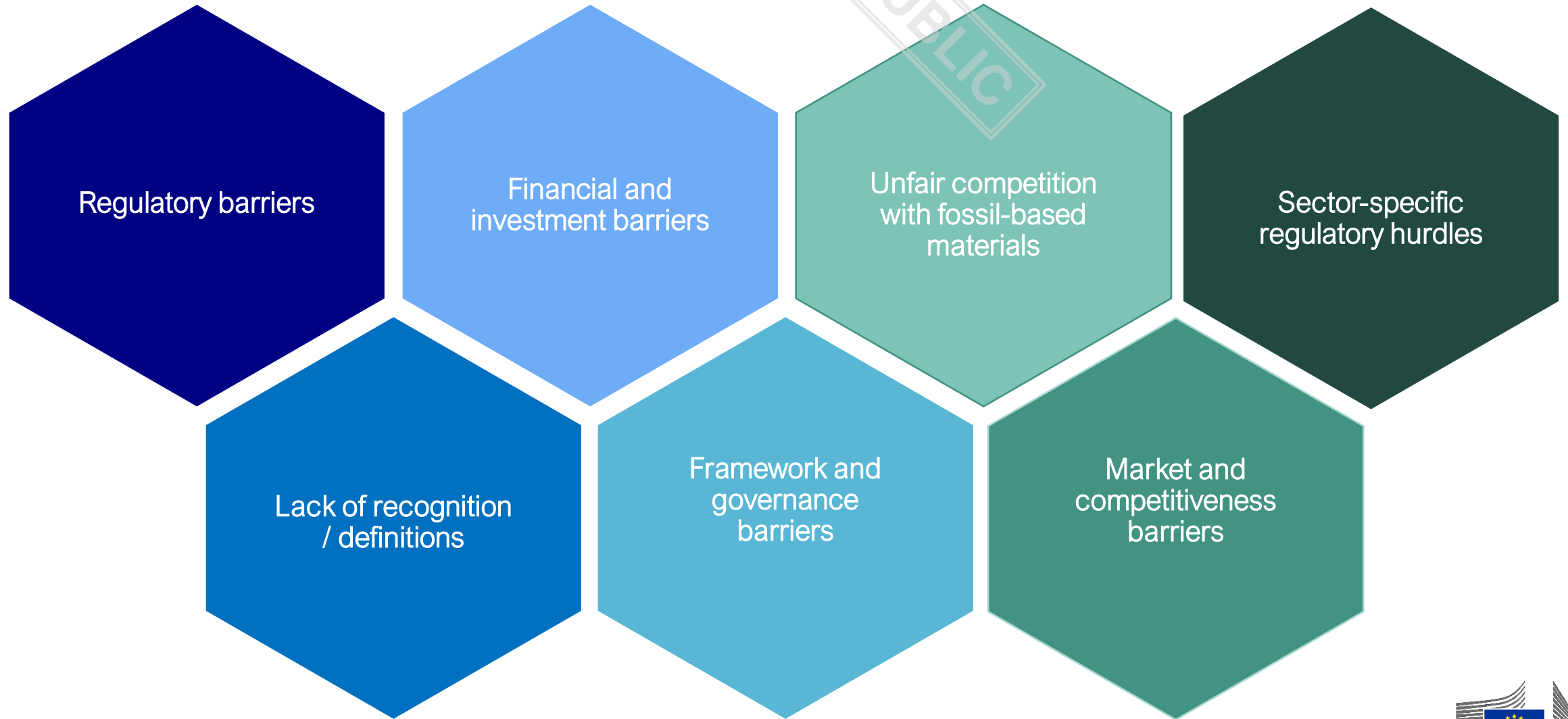
Regarding the challenges to the EU bioeconomy, the risk labelled **“Loss of competitiveness of the sector due to an altering landscape and uncertain regulatory framework”** was identified as most important by the participants

**“Improve policy consistency and harmonisation between EU and national regulations and reduce administrative burden“** was seen as the most needed among regulatory and policy measures, with 208 (57%) respondents answering that this measure is **“Very Important”**

How important is it to improve policy consistency and harmonisation between EU and national regulations?

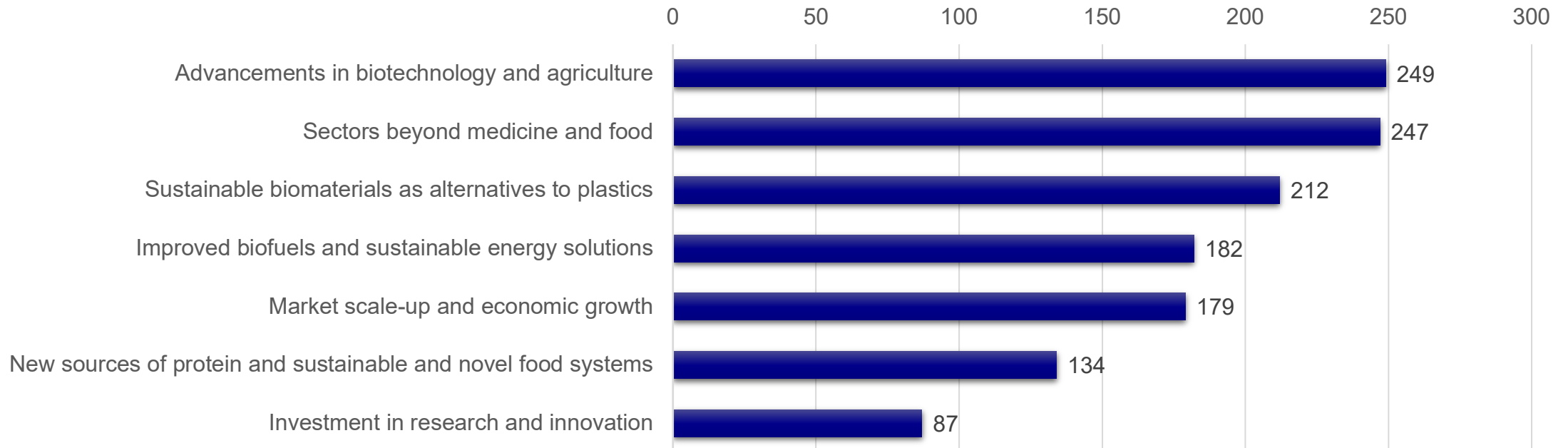


# General barriers identified through the Public Consultation



# Key areas of innovation and opportunity

The new EU Bioeconomy Strategy should use the opportunities and innovation potential of (multiple answers possible)





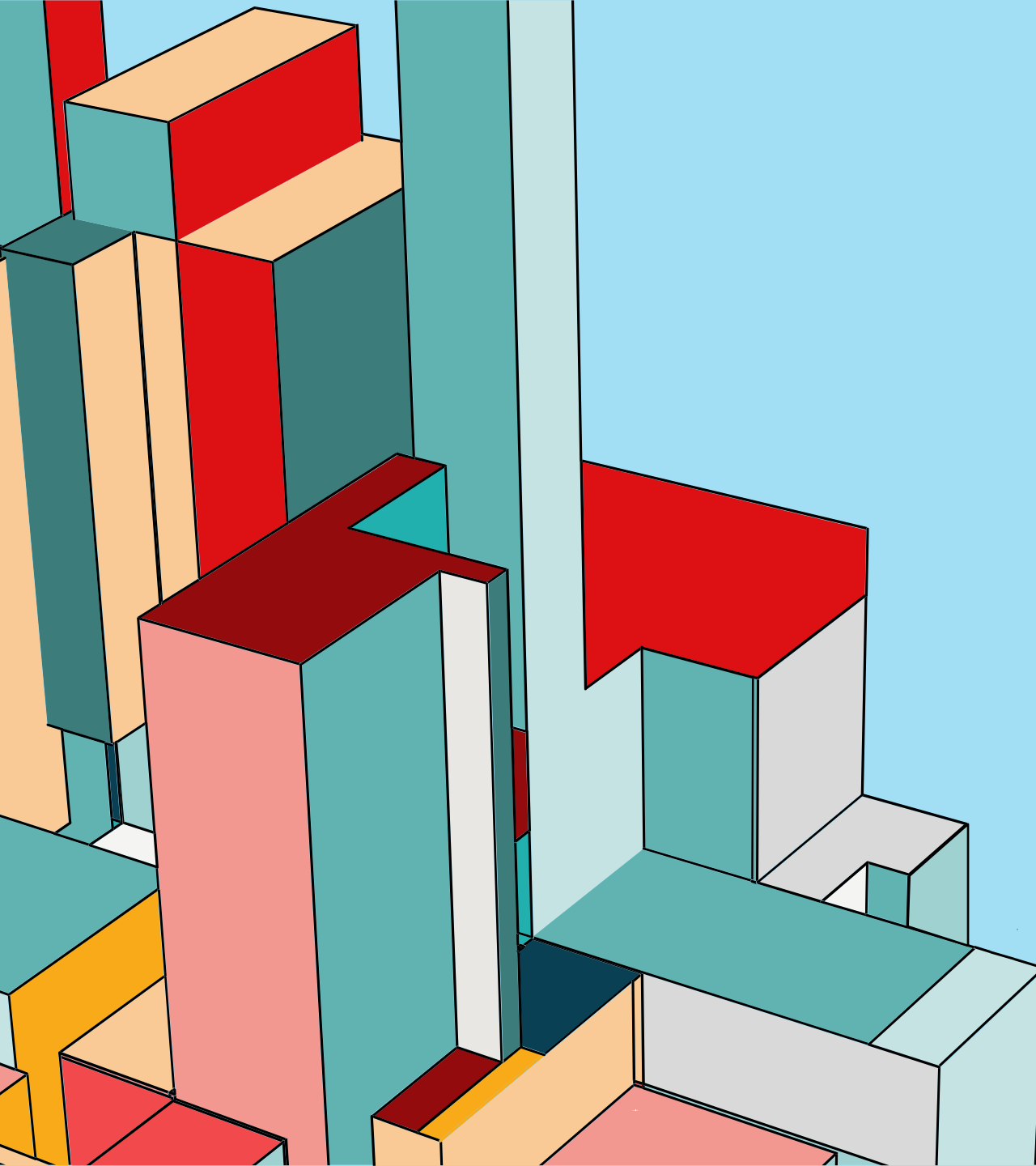
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Thank you!

[Environment - Bioeconomy Strategy](#)

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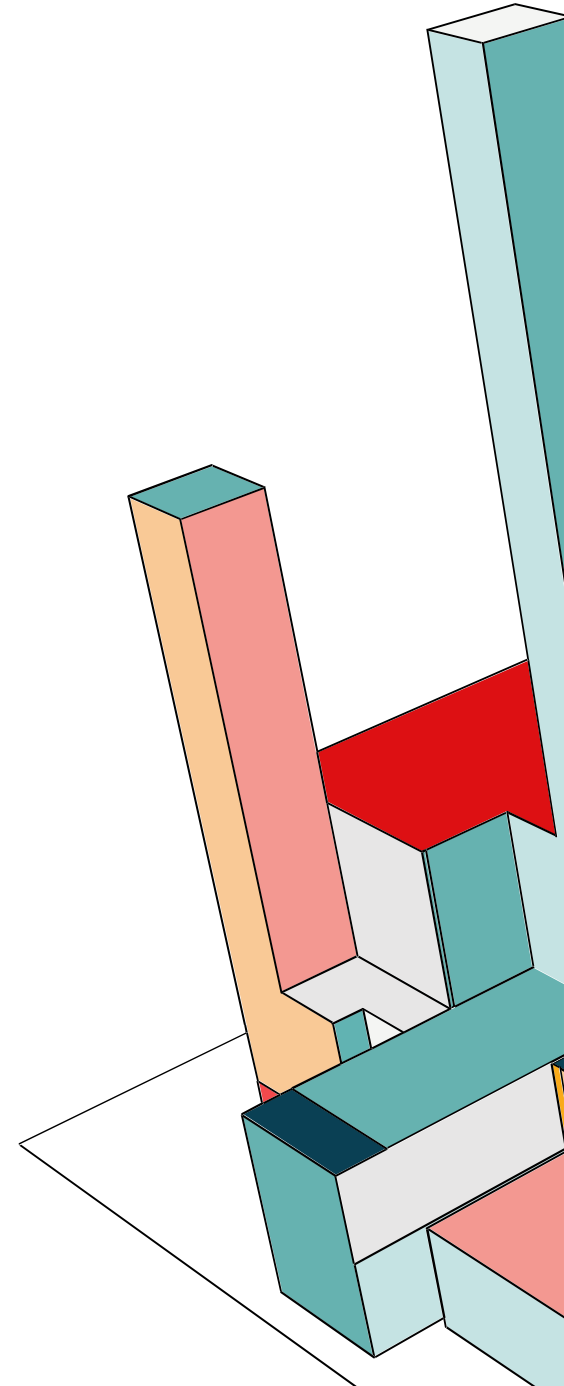
# BIOTECH ACT

INDUSTRY WORKING PARTY  
22 SEPTEMBER 2026

# AGENDA

- Context
- State of play and organisation of the work
- Analysis of Call for Evidence feedback
- Update on studies

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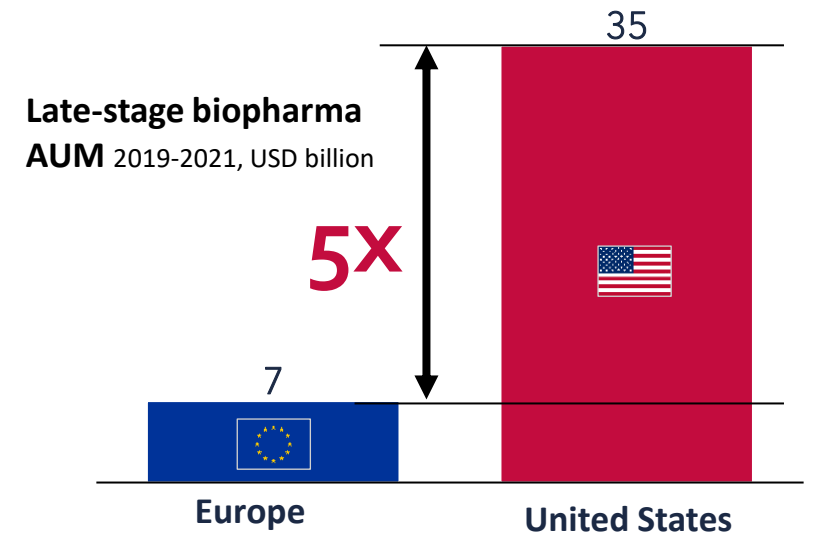
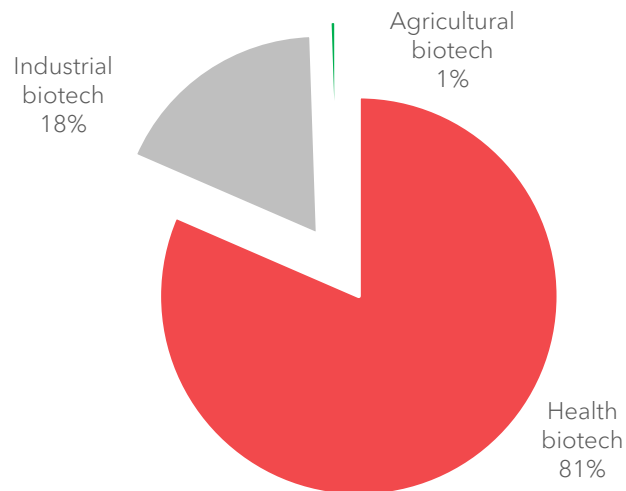
# POLITICAL & ECONOMIC CONTEXT

## POLITICAL CONTEXT

- **Council** 'awaits the announced European Biotech Act and urges the Commission to unlock the broad opportunities offered by this key technology.' (COMPET Council Conclusions, Aug. 2025)
- **EP's** two own initiative reports calling for a broad Commission proposal (ITRE & SANT)
- **Draghi report** (Sept 2024): highlights need to boost the attractiveness of the EU for conducting clinical trials and to expedite access to markets for biotech products

## ECONOMIC CONTEXT

- Biotech: 'Application of science and technology to living organisms to alter materials'
- Pharma biotech largest sector, industrial fastest growing
- EU has strong science (comparable to US), but lags in commercialisation



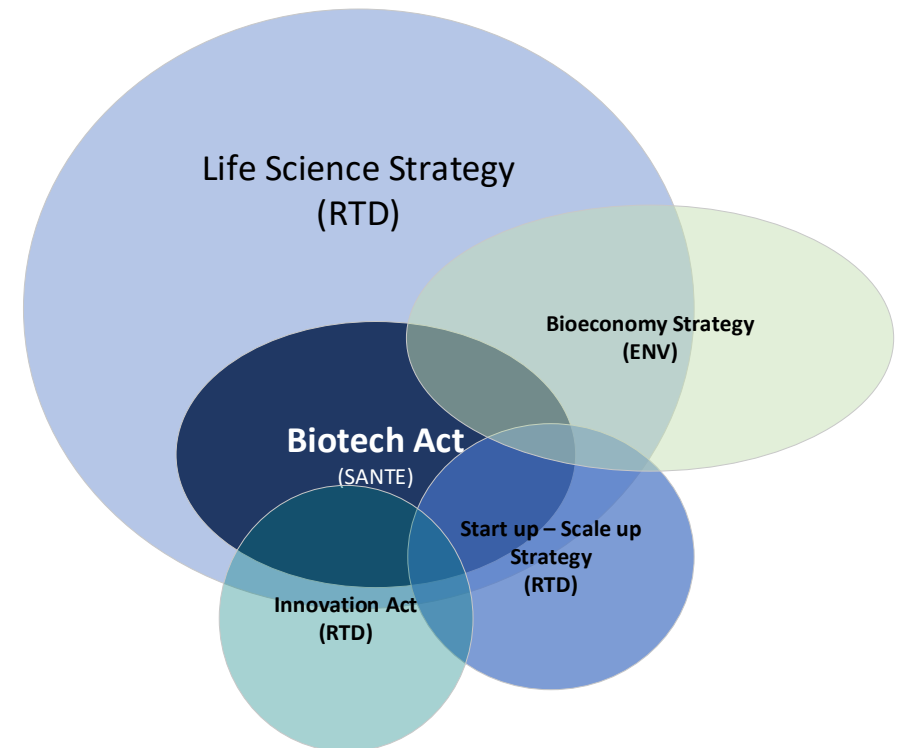
# STATE OF PLAY



- Call for Evidence closed - analysis close to final
- Public Consultation until 10/11
- Support studies:
  1. **Regulatory challenges** - ending in 2025
  2. **Landscape Analysis** - started in August, ending in February 2026
  3. **Policy scenarios impact study** - contract signature in October
- Ongoing outreach: MS , industry, academia

# ORGANISATION OF THE WORK IN THE COMMISSION

- In DG SANTE
- Across the Commission: interservice coordination



# SYNERGIES WITH OTHER INITIATIVES

Several EC initiatives announced in the areas of: life sciences, bioeconomy, and innovation

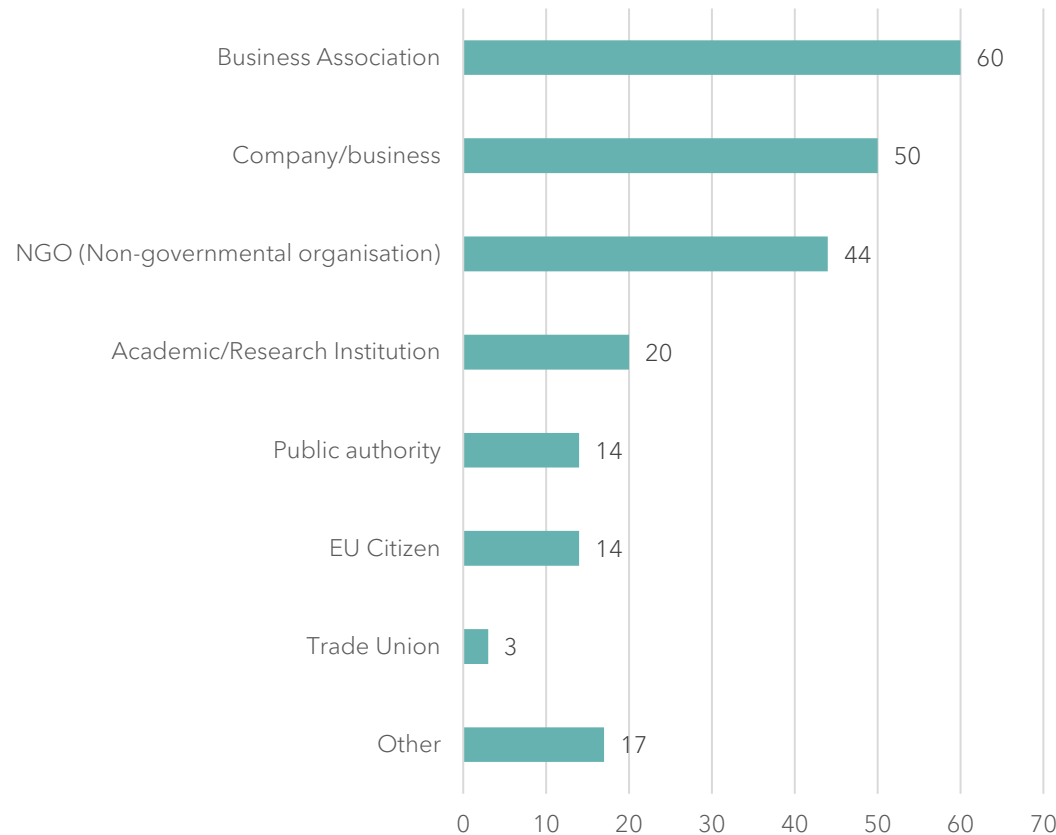
- Close collaboration among Commission services on related initiatives

EU Biotech Act:

- Only legislative instrument specific to the sector
  - Legal instrument: exploring regulatory simplification+ industrial policy 'Act' measures
  - Communication: announcing a series of non-legislative actions
- Scope: applying to all biotech sectors, with emphasis on health biotech

# CALL FOR EVIDENCE ANALYSIS

222 contributions and 148 position papers were received, with half coming from private sector actors and one-third from non-profit organisations



- 222 valid responses\*
- **Half of the respondents are private sector actors** (companies, business associations, or trade unions)
- Majority of 'NGOs' and 'Other' are **not for profit organisations** - together they represent **one-third** of the respondents
- **9% academic and research institutions**
- **6% public authorities**
- **6% EU citizens**

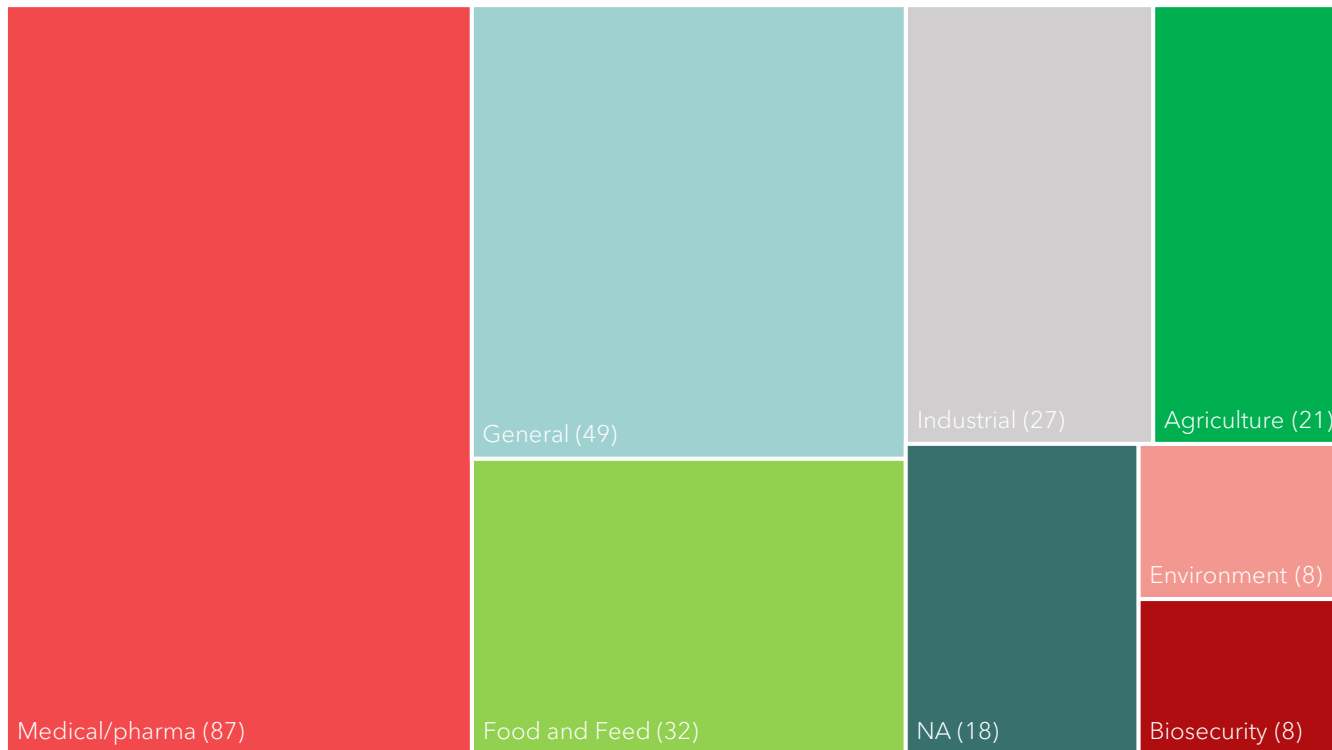
Analysis ongoing and may be subject to changes

\*Three submissions were received from a single respondent and have been counted as one response. Two further submissions were received from another respondent and have likewise been counted as one response. As a result, the total number of responses considered in this analysis is 222 instead of 225.

# CALL FOR EVIDENCE ANALYSIS

Most responses focused on medical and pharma biotech, with food, industrial and agriculture also strongly represented.

Number of responses addressing biotech area (includes multiple categorisation <sup>(1)</sup>)



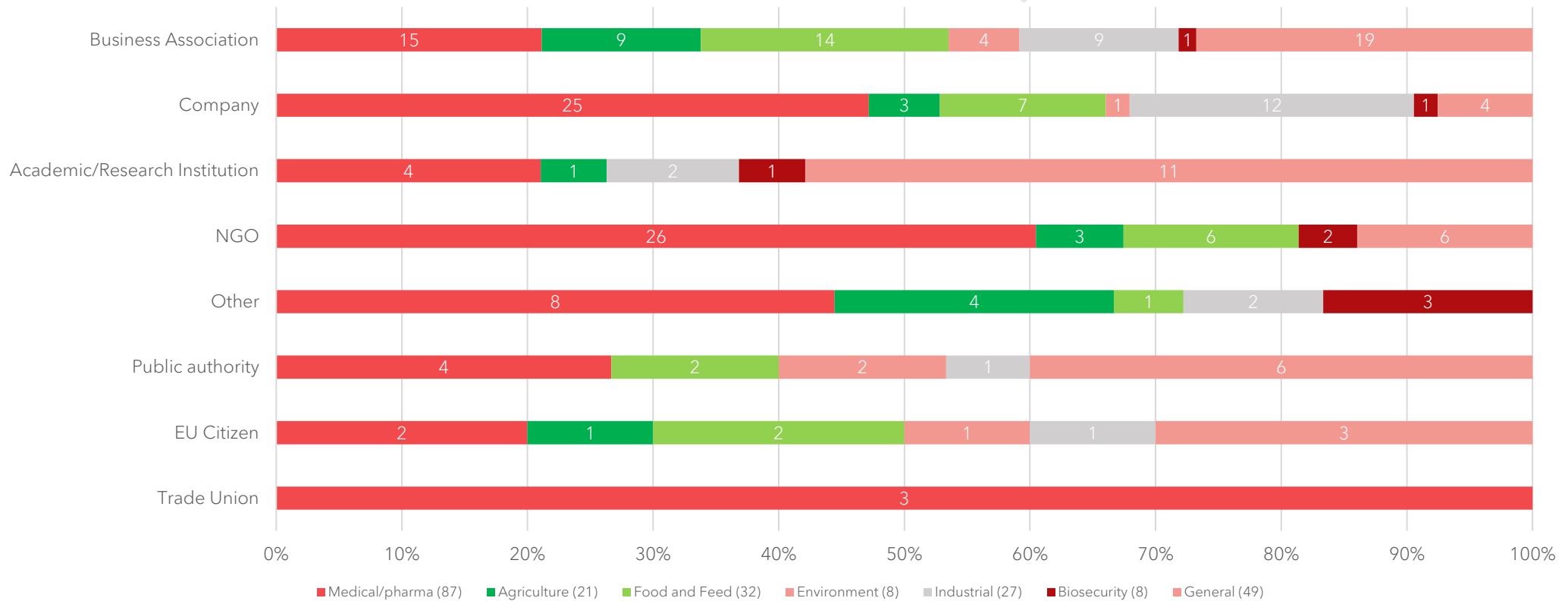
- 35% medical/pharma
- 13% food and feed
- 11% industrial biotech
- 9% agriculture
- 3% each on environment and biosecurity
- 20% 'general'

Source: Technopolis Group based on the call for evidence, N= 250

# CALL FOR EVIDENCE ANALYSIS

Stakeholder focus is diverse: NGOs mostly on medical/pharma, businesses spanning multiple areas, and academia highlighting general aspects

Biotech focus<sup>(1)</sup> by stakeholder category



Source: Technopolis Group based on the call for evidence, N= 250

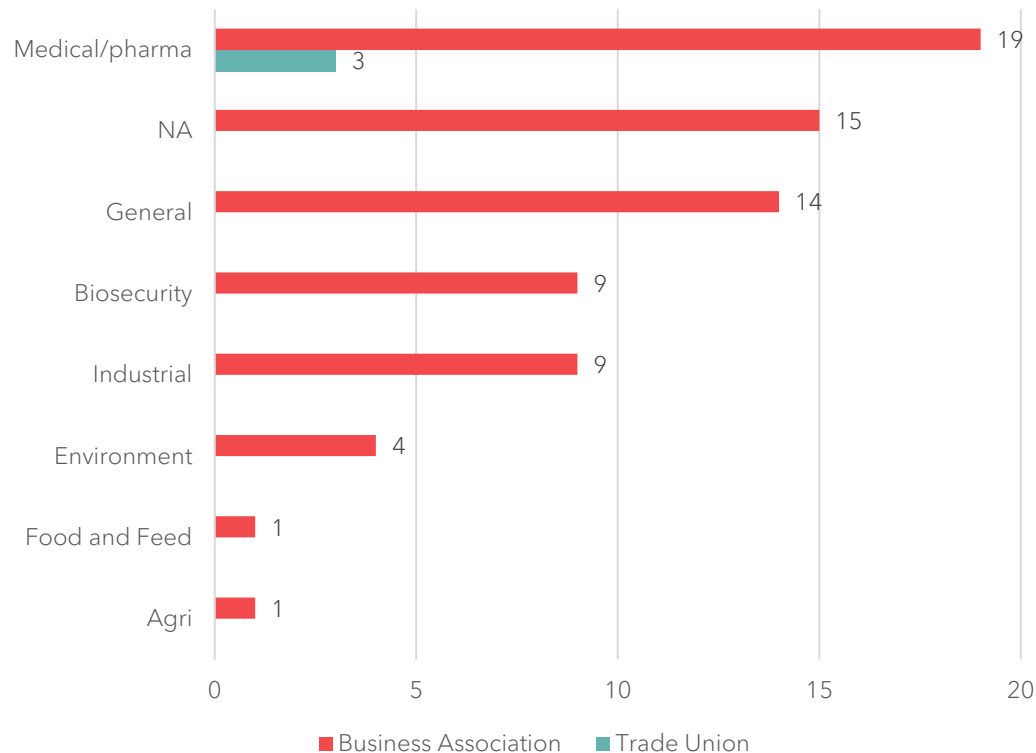
# CALL FOR EVIDENCE ANALYSIS

## Main takeaways – Business Associations and Trade Unions

Business association' inputs span multiple sectors, with General, Medical/Pharma and Food & Feed most represented. <sup>(1)</sup>

Trade union inputs are limited, with only three contributions, all from the Medical/Pharma sector.

Distribution of Business Associations and Trade unions by sector



Source: Technopolis Group based on the call for evidence, N= 75

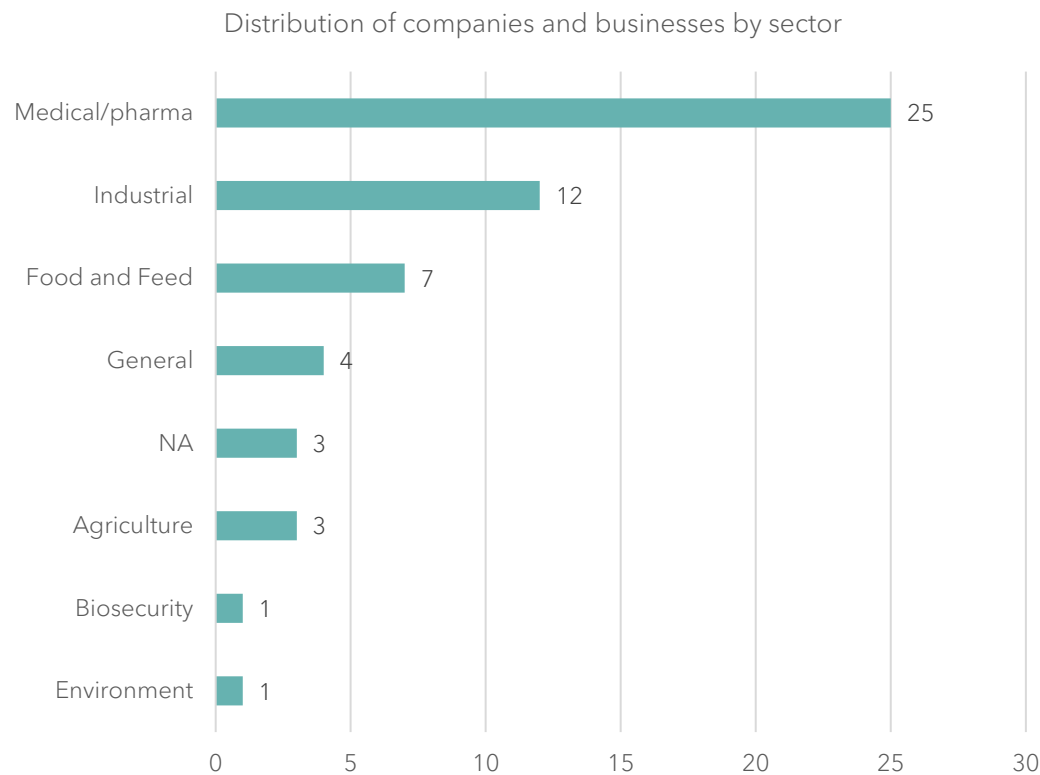
- Broadly supportive of a **European Biotech Act** as a tool to close competitiveness gaps and translate science into industry.
- Strong call for **simpler, more predictable regulation**
  - Streamlined approvals, risk-based approaches, regulatory sandboxes.
- **Financing and scale-up challenges** highlighted
  - Lack of late-stage capital, high production costs, need for EU funds, pilot facilities, and procurement support.
- Shared concern over **skills shortages**
  - Demand for training in regulatory science, AI, data, advanced biomanufacturing, plus global talent attraction.
- Emphasis on **infrastructure and supply chains**
  - Open-access hubs, distributed production, secure raw materials.
- Push for **digital integration**
  - AI, digital twins, European Health Data Space, with secure data access and trust frameworks.
- **Agriculture & food views diverge**
  - Some favour genomic techniques, others call for strict traceability.
- Non-EU associations echoed EU-27 concerns, with extra focus on **cross-industry products and supply chain security**.

# CALL FOR EVIDENCE ANALYSIS

## Main takeaways – Companies and businesses

Biotech Act is seen as a chance to strengthen Europe’s biotech leadership, provided regulation, funding, and skills gaps are addressed.

Inputs are primarily on and from medical/pharma sector, followed by industrial, food and feed. <sup>(1)</sup>



Source: Technopolis Group based on the call for evidence, N= 56

- **Broad support for the Biotech Act** as a tool to restore EU competitiveness while upholding safety standards.
- **Regulatory performance a major concern**
  - Fragmentation, delays, duplicative requirements; calls for a single pathway, clear timelines, early advice, risk-based assessments.
- **Financing and scale-up challenges**
  - Weak late-stage capital, need for incentives, guarantees, de-risking of pilot/demo/manufacturing investments.
- **Infrastructures, quality and skills gaps**
  - Demand for open-access bioproduction hubs, modernised facilities, stronger quality control, and EU-wide training in biotech, data, AI and regulatory science.
- **Sector-specific issues:** faster, predictable health approvals; alignment with HTA; smoother pathways for biocontrol, advanced plant breeding; resilient and decentralised manufacturing.
- **Non-EU contributions echo EU-27 concerns** while stressing sustainable feedstocks, regenerative models, and Europe’s global biotech leadership.

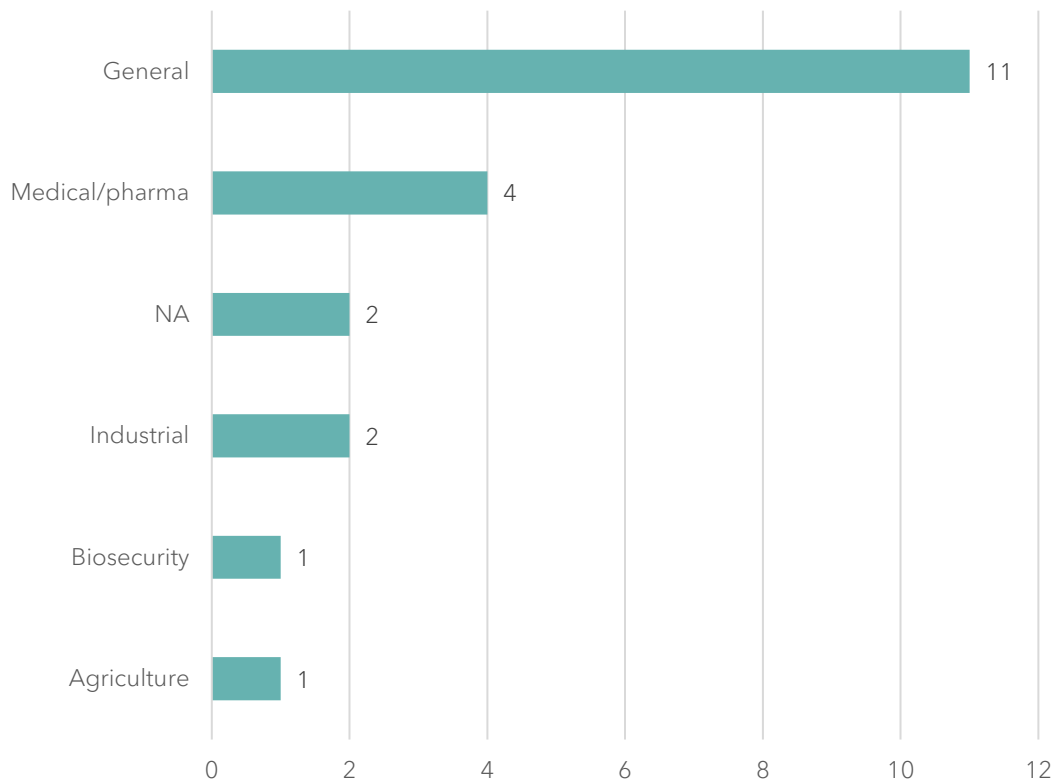
# CALL FOR EVIDENCE ANALYSIS

## Main takeaways – Academic and research institutions

Welcome Biotech Act, but warn of funding gaps, regulatory barriers, and weak research-to-market translation.

Inputs are **mostly of a general nature**, followed by medical/pharma issues.<sup>(1)</sup>

Distribution of Academic and Research Institutions by sector



Source: Technopolis Group based on the call for evidence, N= 21

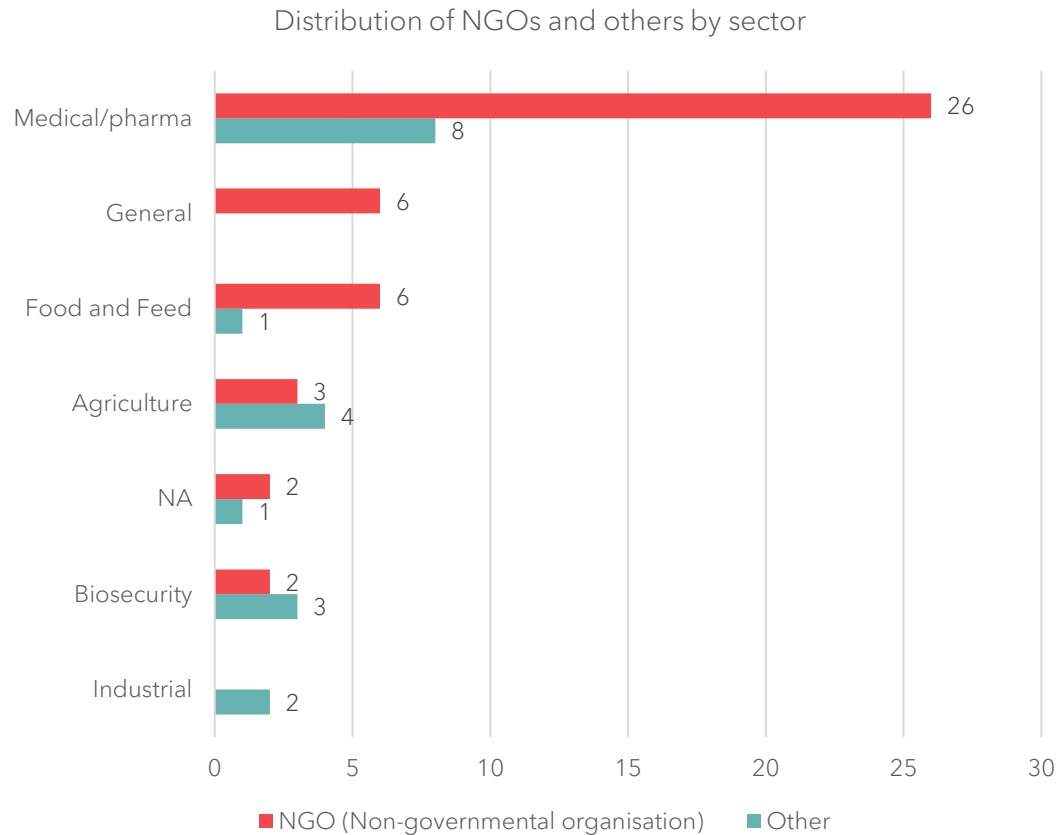
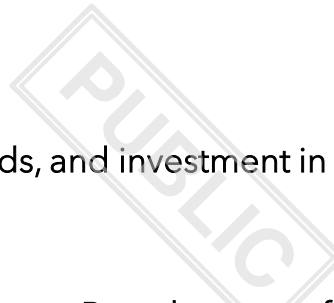
- ❏ **Broad support for the Biotech Act**, stressing biotechnology's cross-cutting potential across health, agri-food, environment and industry.
- ❏ **Funding and capital market deficit** seen as a major barrier
  - ❏ Weak late-stage investment, fragmented markets, underdeveloped financial infrastructure.
- ❏ **Regulatory barriers persist**
  - ❏ Fragmentation, lengthy authorization processes, inconsistent requirements; calls for harmonisation, simplification, and sandboxes.
- ❏ **Bridging the gap from research to market**
  - ❏ Need for consistent funding, pilot/demo infrastructures, and stronger academia-industry collaboration.
- ❏ **Skills and talent development**
  - ❏ EU-level training, mobility schemes, and interdisciplinary education linking biotech, digital and engineering.
- ❏ **Strategic role of biotechnology**
  - ❏ Linked to bioeconomy, sustainability, climate neutrality, resilience and sovereignty, with calls for EU alignment.

# CALL FOR EVIDENCE ANALYSIS

## Main takeaways – NGOs and others

NGOs broadly support the Biotech Act, stressing access, equity, safeguards, and investment in unmet needs.

Input from NGOs and others' **primarily on medical/pharma** issues.<sup>(1)</sup>



Source: Technopolis Group based on the call for evidence, N= 64

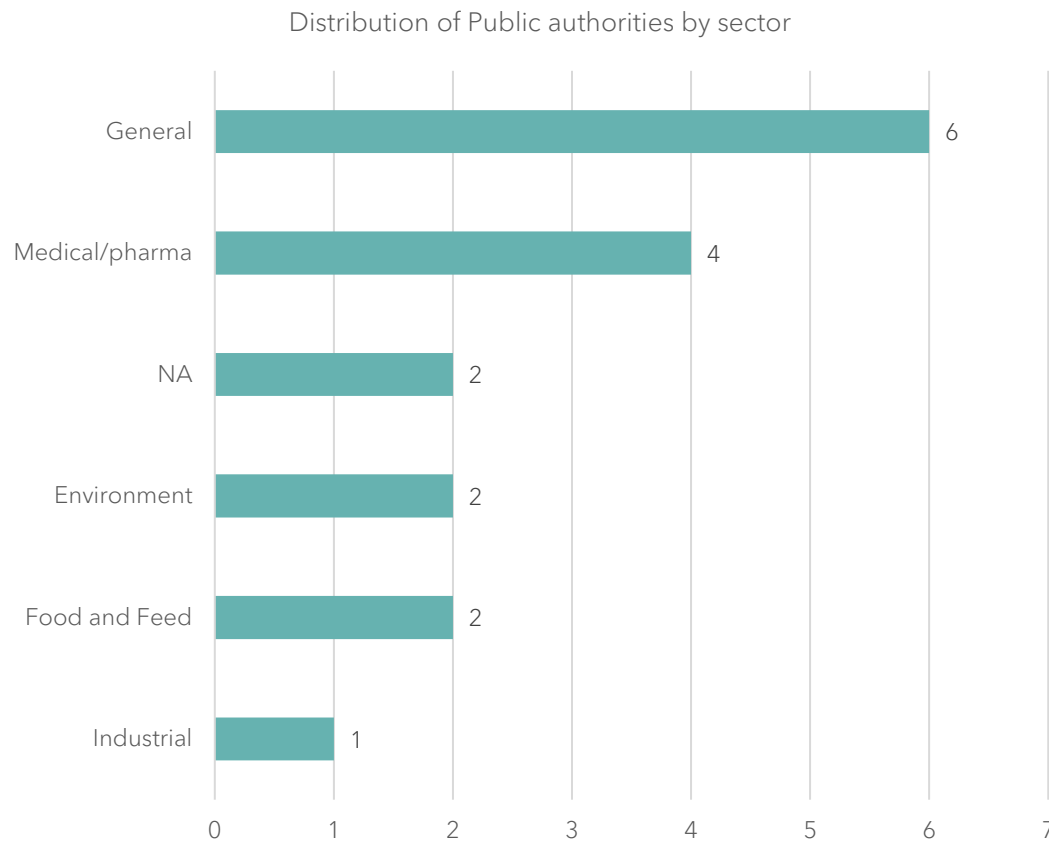
- **Broad support for the Biotech Act**, with emphasis on access, affordability and equity.
- **Patient groups demand systematic involvement in governance**, priority-setting and regulation.
- **Social insurers stress safeguards**: fair pricing from public investment, sustainable funding, and payer dialogue.
- **Focus on unmet needs**: rare diseases, pediatric oncology, women’s health, mental health, AMR.
- **Calls for infrastructure and skills**: GMP facilities, EHDS, trial networks, training in biotech, AI and regulatory science.
- **Diverging views on agriculture**: some warn on GM deregulation, traceability and ecological risks (IFOAM, POLLINIS).

# CALL FOR EVIDENCE ANALYSIS

## Main takeaways – Public authorities (17 responses)

Regulators welcome the Biotech Act; highlight complexity, cross-border inconsistencies, and the importance of risk assessment.

Public authorities' inputs span multiple sectors, with General and Medical/Pharma most represented.<sup>(1)</sup>



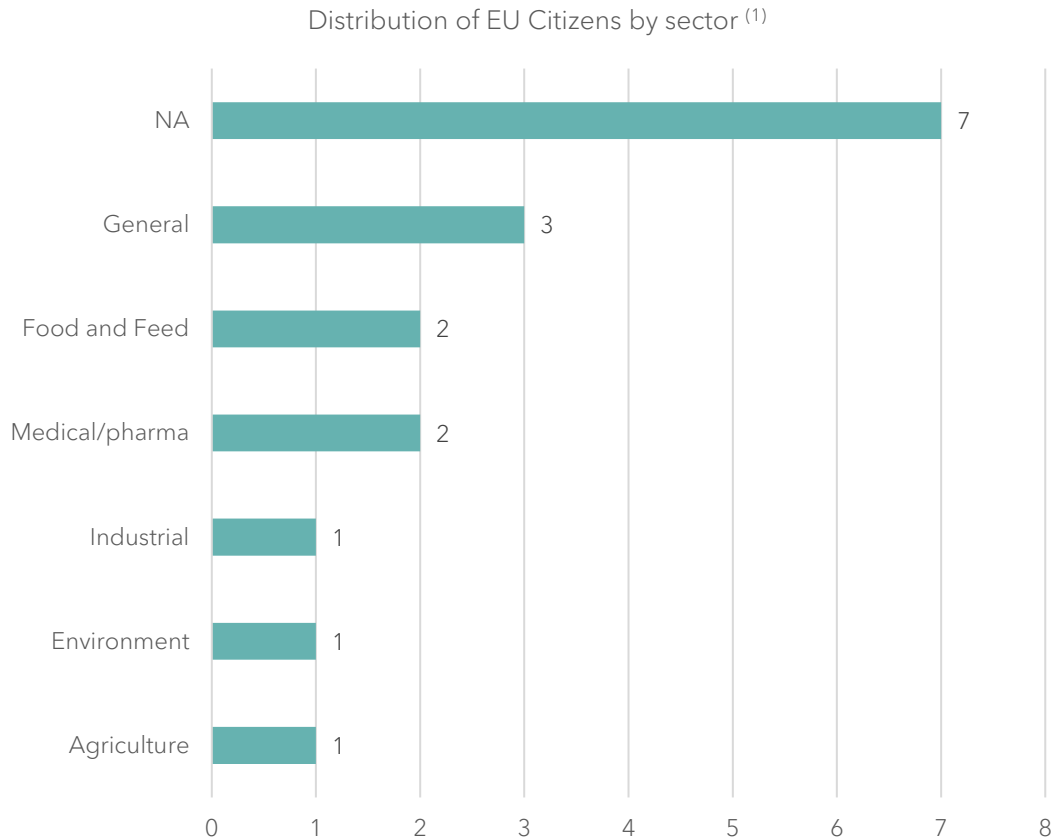
Source: Technopolis Group based on the call for evidence, N= 17

- **Broad support for the Biotech Act**, with emphasis on regulatory clarity, adequate resources, and safeguarding public health and the environment.
- **Regulatory streamlining and convergence** needed to reduce fragmentation, overlaps, and delays in clinical trials and market entry.
- **Harmonised cross-border rules** for research and biological samples, with some support for flexible tools like sandboxes and living labs.
- **Risk assessment and safety central**
  - Calls for independent research on environmental impacts of GMOs/NGTs and horizon-scanning for emerging applications, including AI.
- **Link to EU strategic objectives**
  - Climate neutrality, resilience, industrial transformation, and addressing regional imbalances.
- **Sector-specific measures requested**
  - Distinct frameworks for health, agriculture and food, with simplified procedures and SME support.

# CALL FOR EVIDENCE ANALYSIS

## Main takeaways – EU citizens (17 responses)

Citizen views are divided: some highlight financing gaps, innovation potential and healthcare needs, while others express mistrust and opposition to biotechnology.



Source: Technopolis Group based on the call for evidence, N= 17

- ❏ **Mixed reactions to the Biotech Act**, with both support and opposition expressed.
- ❏ **Financing and competitiveness gaps**
  - ❏ Underfinancing of start-ups, risk-averse venture capital, high outsourcing costs; calls for streamlined regulation, patenting, and better funding tools.
- ❏ **Need for simpler research support**
  - ❏ Current EU funding calls seen as complex and costly; proposals for tailored grants, mentoring, and biotech-specific early-stage funding.
- ❏ **Innovation priorities**
  - ❏ Support for plant-based production, microbial and cell culture technologies, and AI integration, but concerns about inadequate infrastructure and skills.
- ❏ **Public trust as a barrier**
  - ❏ Respondents highlight mistrust, misinformation, and resistance to GMOs and cultured meat; call for stronger science-based communication.
- ❏ **Healthcare concerns**
  - ❏ Emphasis on paediatric oncology, with demands for tailored incentives, regulatory pathways, and funding for rare childhood cancers.

# SUMMARY ANALYSIS OF THE CALL FOR EVIDENCE

## PROBLEM

## DRIVERS / CAUSES

## AREAS OF INTERVENTION

## SPECIFIC OBJECTIVES

## GENERAL OBJECTIVES

**Complexity: slow time to market**

Heavy regulatory frameworks

Rapidly evolving & high-risk sectors in biotech, accelerated by AI & data

**Regulatory simplification & future proofing**

Reduce biotech products time to market, alleviating administrative burden (incl. for SMEs)

**Competitiveness**

**Risk tolerant capital**

Facilitate access to adequate financing and reduce the risk financing gap with US/others

**Societal wellbeing (health, food, sustainability)**

**Skills**

Increase the use of key resources for growth and innovation in the sector (AI & data, skills)

**Fragmentation: small scale**

Scattered expertise (e.g. clusters spread across Europe, not pooling capacities)

**AI & Data**

Strengthen biomanufacturing infrastructures and enable EU centers of excellence to compete at global scale

**Strategic autonomy & security**

Access to capital and infrastructure difficult & limited vs other jurisdictions - some start-ups and scale-ups move abroad to scale

**Clusters/ biomanufacturing**

**Biosecurity & Biodefence**

Leverage biotech advances for defence and safeguard dual-use technologies against misuse

EU is facing a major **competitiveness gap** in biotech, despite being a leader in science

Biotech potential to contribute to major societal challenges & EU strategic autonomy & security is underexploited

# PRELIMINARY RESULTS OF THE STUDY ON REGULATORY CHALLENGES

## Pillar A

Collect evidence on various concrete policy options (e.g. clinical trials) to be directly used in an impact assessment.



No intermediate results on any of the options are available yet.  
Data collection and assessment of the options using cost-benefit analysis **is still ongoing**

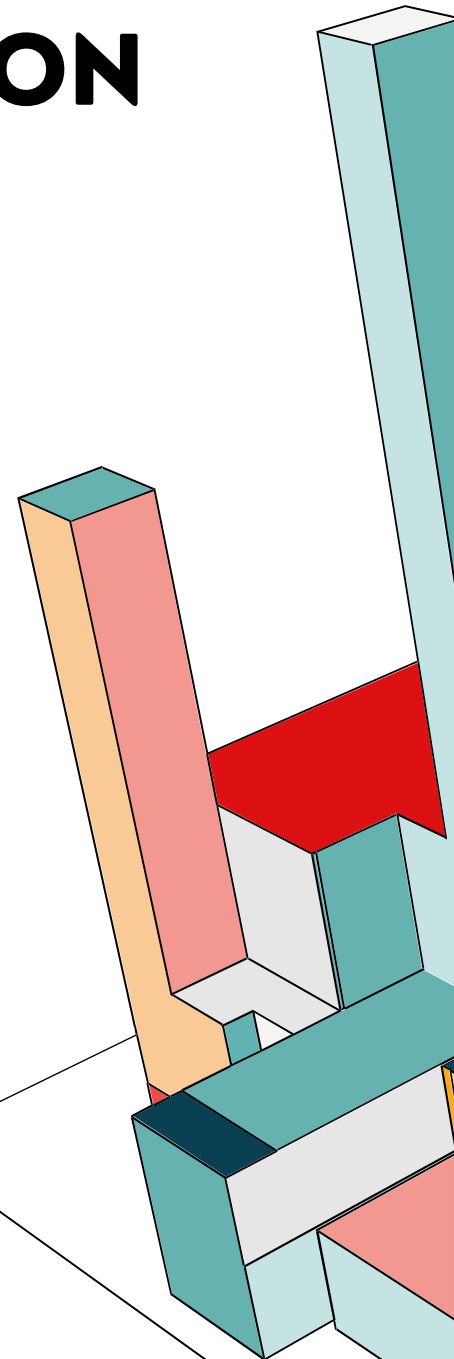
## Pillar B

Collect data and information on (regulatory) challenges faced by the biotech and biomanufacturing sectors linked to EU or national legislation.



200 unique challenges stemming from 80 pieces of EU legislation identified and grouped in 8 categories

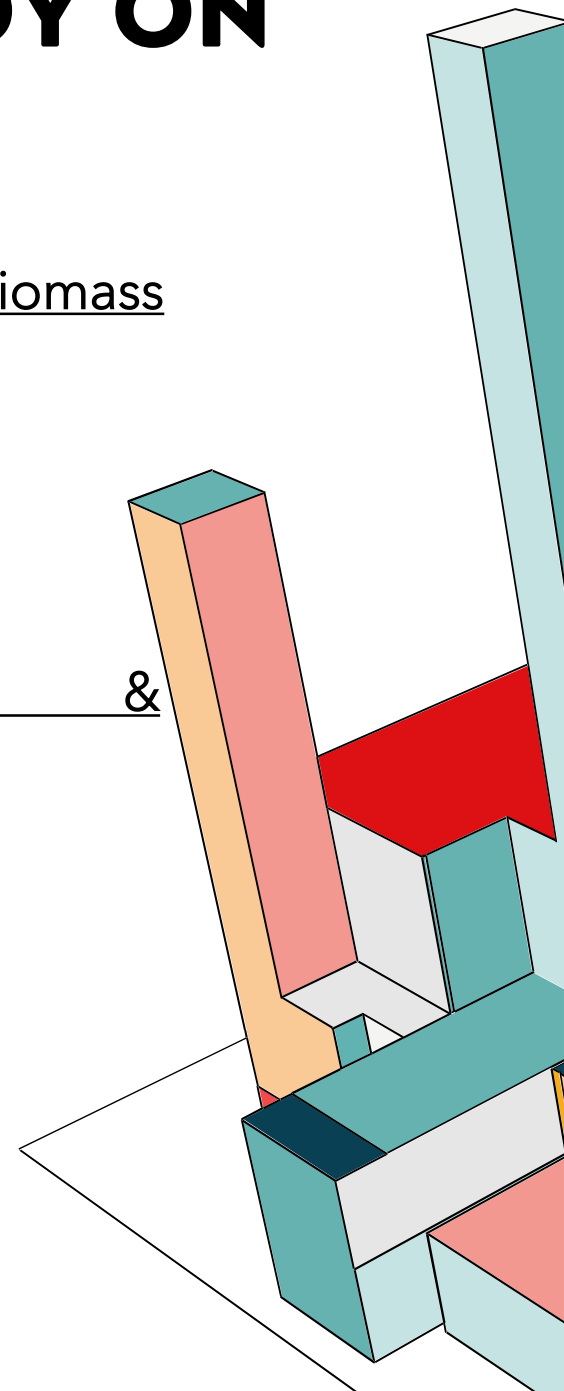
Sectors: health/pharma, agriculture, food/feed, chemicals, detergents, cosmetics, biomanufacturing and research.

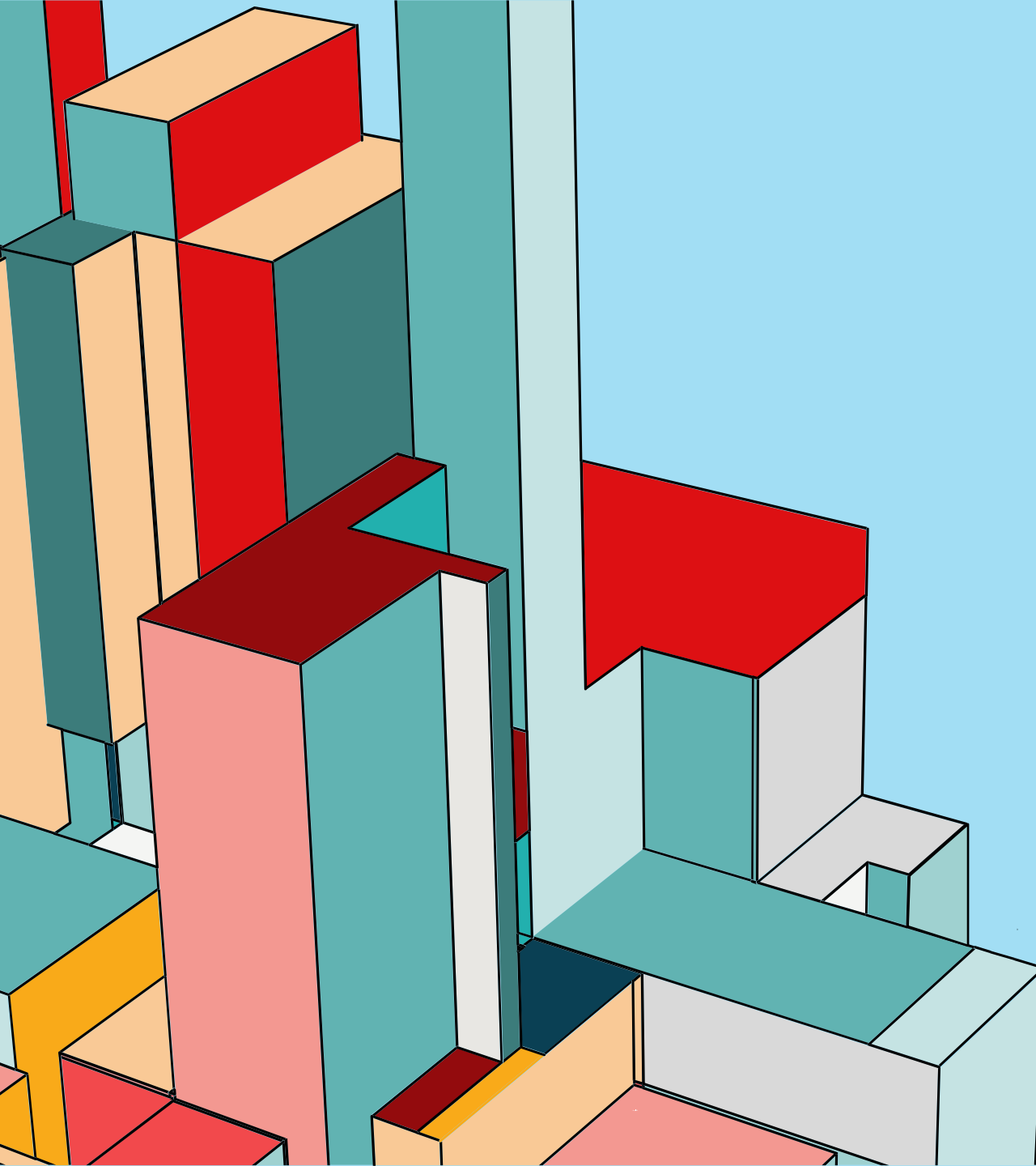


# PRELIMINARY RESULTS OF THE STUDY ON REGULATORY CHALLENGES

- Strategic alignment & market pull
- Finance, fiscal incentives & infrastructure
- Feedstock/biomass access
- Approval pathways
- Definitions & guidance
- Regulatory capacity & timelines
- Intellectual property protection
- Regulatory scope & permitting

PUBLIC





**THANK YOU**

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