2 Challenges and Potential areas for simplification

This section aims **to identify the regulatory challenges and impacts faced by stakeholders across the biotechnology and biomanufacturing value chain** (i.e. research, development, manufacturing, commercialisation and/or market placement).

Please note that the survey allows you to add challenges individually, enabling a deeper exploration of each **individual legislation-related challenge.**

2.1 Legislation-related challenge 1

* 2.1.1 Is there any legislation or connected implementation or enforcement measure at the EU and/or national level that is posing challenges to you or your member's activity?

- (●) Yes
- ( ) No

* 2.1.2 Which legislation-related challenge do your organisation or your members face? (if possible, please refer to the specific legislation(s) at either EU or national level, to which this challenge is connected)

A major legislation-related challenge we face concerns the applied definition of "natural polymers" under the EU's legislative framework stemming from REACH Regulation (2008), the subsequent ECHA Guide (on monomers and polymers) 2012/2023, and Single Use Plastic Directive (2019) combined. This definition excludes polymers synthesized through industrial bioprocesses, even if they are chemically identical to naturally occurring polymers. Besides being overly restrictive, the definition lacks scientific grounding, requiring natural polymers to be "polymerized in nature", despite their identical composition, excellent environmental profiles, and potential for scalable, sustainable innovation. This limitation stifles material innovation and creates an uneven playing field, as such polymers are treated the same as conventional plastics. The cumulative effect is a regulatory landscape that penalises innovation, undermines sustainability goals, and places biotech and biomanufacturing organisations at a systemic disadvantage.

* 2.1.3 What impact does this challenge have on your organisation or your members (e.g. costs, time spent, competitive disadvantages, time to market issues, etc.)? (if possible, please provide a quantification and examples to the identified impacts)

This is a substantial challenge with negative impacts of being labelled as “plastics” by default. The restrictive definition of natural polymers creates major market and regulatory barriers for bio-based material innovators and companies that want to move to more sustainable alternatives to conventional plastics. Biopolymers produced through biomanufacturing are misclassified as “plastics,” making them subject to the same bans and compliance burdens as conventional fossil-based materials. This increases costs, delays product development, and limits market access. The misclassification also harms perception—reducing consumer acceptance and creating reputational risk. These issues spill over into multiple EU policies, including PPWR, Food Contact Materials, Microplastics in Drinking Water, and Fertilising Products Regulations, putting biotech and bioeconomy actors at a systemic competitive disadvantage.

* 2.1.4 Is this challenge affecting your organisation’s or your member’s competitiveness at the national, EU or international level (please select all that apply)?

- [x] National level
- [x] EU level
- [x] International level
- [ ] No impact

* 2.1.5 Are you aware if similar organisations (outside the biotechnology/biomanufacturing sectors) face the same challenge?

- ( ) Yes (please specify)
- (•) No

* 2.1.7 How would you like to see the identified challenge addressed by legislators or public administrations?

1. The EU regulatory framework must evolve to reflect scientific progress and support innovation in bio manufactured materials. Instead of relying on place-based definitions of “natural polymers,” a criteria-based approach—considering origin, properties, impact, and safety—should guide material assessment. This is already seen in the REACH microplastics restriction and EU Fertilising Products Regulation, where biodegradability and performance tests are used to evaluate materials for environmental performance and safety. Extending this criteria as a harmonized material assessment approach would allow fair evaluation of bio-manufactured and nature-identical materials by reducing unnecessary regulatory burdens and incentivize adoption.

2. Until a harmonised criteria and test methods are developed to assess non-persistence, functionality, and safety of materials for products, it may be beneficial to align the interpretation of "natural polymer" from REACH in legislations like PPWR and SUPD with the approach in the Flavourings Regulation (EC 1334 /2008)—recognising materials made via microbiological or enzymatic processes as natural. Applying a similar logic to polymers could ensure that materials produced via biotechnological methods are appropriately recognised for their properties and applying blanket plastic policies may be avoided.

3. The upcoming REACH revision is a key opportunity to revise the definition of natural polymers and enable biotech innovations, like PHAs, to be fairly assessed—removing unnecessary regulatory hurdles, promoting investment, and supporting a circular bioeconomy.

* 2.1.8 Are you aware of instances where the regulatory challenge was resolved with the support of authorities?

- ( ) Yes

- (●) No

2.2 Legislation-related challenge 2

* 2.2.1 Is there any additional legislation or connected implementation or enforcement measure at the EU and /or national level that is posing challenges to your or your member's activity?
  - (●) Yes
  - ( ) No

* 2.2.2 Which legislation-related challenge do your organisation or your members face? (if possible, please refer to the specific legislation(s) at either EU or national level, to which this challenge is connected)

> Under the EU Packaging and Packaging Waste Regulation (PPWR, 2025), the limited scope of the positive list for compostable materials provides significantly restricted scope for compostable packaging—even when such materials meet rigorous environmental and performance criteria. This creates a barrier for the adoption of biotech-driven, biodegradable innovations such as PHA biopolymers, particularly in mass-producing sectors like packaging, where scalable impact is most needed. Furthermore, the lack of harmonised criteria for microplastics means that non-persistent and biodegradable materials are often treated identically to persistent plastics across regulations.

* 2.2.3 What impact does this challenge have on your organisation or your members (e.g. costs, time spent, competitive disadvantages, time to market issues, etc.)? (if possible, please provide a quantification and examples to the identified impacts)

> These materials are often misclassified as conventional plastics, resulting in higher compliance costs, delayed approvals, and limited access to packaging markets. This stifles innovation, reduces competitiveness, and discourages investment in sustainable, bio-based alternatives that are ready to scale.

* 2.2.4 If your organisation is a business or industry association,is this challenge affecting your organisation's or your member's competitiveness at the national, EU or international level (please select all that apply)?
  - [x] National level
  - [x] EU level
  - [x] International level
  - [ ] No impact

* 2.2.5 Are you aware if similar organisations (outside the biotechnology/biomanufacturing sectors) face the same challenge?
  - ( ) Yes (please specify)
  - (●) No

* 2.2.7 How would you like to see the identified challenge addressed by legislators or public administrations?

Because packaging is one of the most polluting industries, it's also one of the most important places to introduce compostable and biodegradable substitutes. We recommend utilizing Article 9(5) of PPWR to reassess applications compostability and include all organic and food waste packaging in mandatory compostable list to propose changes that reflects this. Compostable materials, including biotech-derived innovations biopolymers require regulatory backing to create an innovation-friendly market. Additionally, many conventional plastic packaging contaminates the composting cycle today, which creates microplastic pollution in the soil and food systems. These packaging formats are well known and researched, such as small packaging films. These items should be recyclable AND compostable. In this way, they will not contaminate the compost stream.

* 2.2.8 Are you aware of instances where the regulatory challenge was resolved with the support of authorities?

- ○ Yes
- ◉ No

2.3 Legislation-related challenge 3

* 2.3.1 Is there any additional legislation or connected implementation or enforcement measure at the EU and /or national level that is posing challenges to your or your member's activity?

- ◉ Yes
- ○ No

* 2.3.2 Which legislation-related challenge do your organisation or your members face? (if possible, please refer to the specific legislation(s) at either EU or national level, to which this challenge is connected)

The Waste Framework Directive lacks of clarity and distinction between food waste and food wastage, hindering effective strategies for reducing avoidable waste while using unavoidable waste as valuable feedstock for high-value products with innovative biotech. Additionally, the Directive does not sufficiently support the use of compostable and biodegradable materials as tools to boost bio-waste collection. Furthermore, the current definition of recycling does not recognise carbon recycling through composting and anaerobic digestion, discouraging investment in necessary infrastructure and limiting the potential of a circular bioeconomy.

* 2.3.3 What impact does this challenge have on your organisation or your members (e.g. costs, time spent, competitive disadvantages, time to market issues, etc.)? (if possible, please provide a quantification and examples to the identified impacts)

With no strong frameworks recognizing carbon recycling as a valid and valuable recovery route, biobased materials are perceived as a challenge in end-of-life treatments and reject for posing contamination risks despite having multiple end-of-life possibilities, innovative biopolymers are unable to reach their full potential without proper end-of-life waste management systems in place.

* 2.3.4 If your organisation is a business or industry association,is this challenge affecting your organisation's or your member's competitiveness at the national, EU or international level (please select all that apply)?

- ☑ National level

- [x] EU level
- [x] International level
- [ ] No impact

* 2.3.5 Are you aware if similar organisations (outside the biotechnology/biomanufacturing sectors) face the same challenge?
  - ( ) Yes (please specify)
  - (•) No

* 2.3.7 How would you like to see the identified challenge addressed by legislators or public administrations?

1. The Waste Framework Directive must mandate the use of compostable and biodegradable materials in appropriate applications to increase the volume and quality of bio-waste collection. This should be tied to a clear distinction between food waste and food wastage, enabling both targeted prevention and valorisation of unavoidable waste. The success of Italy's national policy—where compostable carrier bags are mandatory for organic waste collection and have significantly boosted bio-waste recovery—demonstrates the effectiveness of such measures.
2. Additionally, the Directive must explicitly recognise carbon recycling—such as composting and anaerobic digestion—as legitimate and impactful forms of recycling. This recognition is essential to unlock investment in end-of-life infrastructure, support harmonised standards, and enable the growth of innovative bio-based materials that depend on biological recycling systems. Without this shift, the EU risks underutilising a key pathway for circularity and climate action.

* 2.3.8 Are you aware of instances where the regulatory challenge was resolved with the support of authorities?
  - ( ) Yes
  - (•) No

2.4 Legislation-related challenge 4

* 2.4.1 Is there any additional legislation or connected implementation or enforcement measure at the EU and /or national level that is posing challenges to your or your member's activity?
  - (•) Yes
  - ( ) No

* 2.4.2 Which legislation-related challenge do your organisation or your members face? (if possible, please refer to the specific legislation(s) at either EU or national level, to which this challenge is connected)

1. JRC's plastics LCA method and Product Environmental Footprint (PEF) LCA: The current LCA frameworks used in the JRC's plastics LCA method and the Product Environmental Footprint (PEF) fail to distinguish the climate benefits of biobased and compostable materials from fossil-based plastics, resulting in an unfair environmental impact comparison.

2. Renewable Energy Directive (RED III) : Both PEF and RED III use a 0/0- (or net zero-)approach—where any biogenic removal and emission count towards the GHG emissions with 0. This means they count both the carbon absorbed by plants (when growing biomass) and the carbon released (when using it) as 0; which is not accurate, as fossil carbon only adds new CO_2 to the atmosphere, while biobased carbon just recycles it. So treating them the same hides the real climate benefits of biobased products and makes comparisons unfair.

3. EU Emissions Trading System (ETS) and the Carbon Border Adjustment Mechanism (CBAM): These currently exclude many downstream bio-based products and organic chemicals. This creates a regulatory blind spot, excluding effective biotech-based climate solutions from incentive structures designed to reduce emissions.

* 2.4.3 What impact does this challenge have on your organisation or your members (e.g. costs, time spent, competitive disadvantages, time to market issues, etc.)? (if possible, please provide a quantification and examples to the identified impacts)

1. When assessments between fossil polymers and biobased materials are compared, biobased materials face challenges due to several complex factors that current LCA methodologies are not designed to address. This results in "apples-to-oranges" comparisons that lack a level playing field, often leading to misleading conclusions. As a result, organisations could be disadvantaged in public procurement, eco-labelling, and regulatory assessments.

2. The exclusion of bio-based downstream materials from ETS and CBAM limits the competitiveness and scalability of low-carbon biotech products, despite their ability to reduce emissions in sectors traditionally hard to decarbonize. For example, CO_2-based PHA biopolymers physically store captured CO_2, but this storage is not recognized in current carbon accounting frameworks. As a result, materials that offer measurable climate benefits through carbon retention are not rewarded or supported under existing regulatory mechanisms. The undervaluation of biogenic carbon benefits also restricts market uptake, and reduces investor confidence by not reflecting the true environmental value of biobased products.

* 2.4.4 If your organisation is a business or industry association,is this challenge affecting your organisation's or your member's competitiveness at the national, EU or international level (please select all that apply)?

- [x] National level
- [x] EU level
- [x] International level
- [ ] No impact

* 2.4.5 Are you aware if similar organisations (outside the biotechnology/biomanufacturing sectors) face the same challenge?

- ( ) Yes (please specify)
- (•) No

* 2.4.7 How would you like to see the identified challenge addressed by legislators or public administrations?

LCA methodologies must provide clear guidance on how to account for benefits of biodegradability and renewable sourcing.
1. Fair comparison b/w bio-based and fossil-based: LCA methods should be fit-for-purpose and tailored to specific sectors or product types, allowing a fair comparison between bio-based and fossil-based materials.
a. This can be done by expanding beyond climate change impact and recognizing overall, long-term environmental impacts of biobased, biodegradable and compostable products. Like including land use, biodegradability, microplastic persistence as part of the guidance in LCAs.
b. developing clear guidance in LCAs on how to demonstrate environmental benefits of non-persistent, biodegradable biopolymers.

2. Refine and enable biogenic carbon accounting w.r.t RED III and PEF Frameworks;
a. Enable biogenic carbon accounting: We recommend framework moving away from the 0/0 approach used in RED III and PEF and accounting biogenic carbon by using a -1/+1 approach for removals and emissions, as it considers bio-based products remove carbon first, unlike fossil products which only emit (+1)
without any removal. This approach shows the circular nature of biogenic carbon and the real climate benefit
of renewable carbon—accurately reflecting the true environmental value of biotech innovations.
b. Recognize microbial CCU emissions as biogenic: Recognize emissions from microbial carbon capture and
utilization processes as biogenic when they occur in a closed biological cycle, with clear guidelines provided
under RED III and future PEF updates.
RED III and future PEF updates can support these systems by highlighting their role in the circular carbon economy and reinforcing the environmental value of renewable carbon.

3. Expand the scope of ETS and CBAM: This should include downstream organic chemicals and bio-based materials, enabling low-emission biotech solutions to benefit from emissions trading incentives and carbon border protection. This could better reflect their emissions reduction potential and foster competitiveness in global markets.

* 2.4.8 Are you aware of instances where the regulatory challenge was resolved with the support of authorities?

- ○ Yes
- ◉ No

2.5 Legislation-related challenge 5

* 2.5.1 Is there any additional legislation or connected implementation or enforcement measure at the EU and /or national level that is posing challenges to your or your member's activity?

- ◉ Yes
- ○ No

* 2.5.2 Which legislation-related challenge do your organisation or your members face? (if possible, please refer to the specific legislation(s) at either EU or national level, to which this challenge is connected)

The biomass-use prioritisation principle introduced under RED III: It creates an unequal regulatory environment by favouring the energy and fuel sectors over the production of biobased materials. This leads to distorted feedstock access and does not reflect the broader sustainability potential of biobased materials such as PHA biopolymers.

* 2.5.3 What impact does this challenge have on your organisation or your members (e.g. costs, time spent, competitive disadvantages, time to market issues, etc.)? (if possible, please provide a quantification and examples to the identified impacts)

This creates feedstock insecurity and price volatility for biotech and biomanufacturing organisations, discouraging investment and scale-up of sustainable materials. It undermines innovation, especially for emerging biopolymer applications by placing them at a systemic disadvantage compared to biofuels. There is a systemic lack of incentives or policy-driven communication to promote the uptake of non-persistent, innovative bio-based materials. In contrast, persistent fossil-based plastics continue to benefit from strong policy support through recycling targets and infrastructure. This creates a policy imbalance that hinders the market development of bio-based, biodegradable materials, despite their superior environmental performance and alignment with EU decarbonization, competitiveness, and circular economy goals.

* 2.5.4 If your organisation is a business or industry association,is this challenge affecting your organisation's or your member's competitiveness at the national, EU or international level (please select all that apply)?

- [x] National level
- [x] EU level
- [x] International level
- [ ] No impact

* 2.5.5 Are you aware if similar organisations (outside the biotechnology/biomanufacturing sectors) face the same challenge?

- ( ) Yes (please specify)
- (•) No

* 2.5.7 How would you like to see the identified challenge addressed by legislators or public administrations?

There should be a level playing field and unfair comparisons must be avoided. It can be achieved by introducing clear, harmonised sustainability criteria for all biomass end-uses— including for materials—as it does for biofuels.

* 2.5.8 Are you aware of instances where the regulatory challenge was resolved with the support of authorities?

- ( ) Yes
- (•) No

2.6 Legislation-related challenge 6