Bioplastics in Medical Devices

Overcoming Challenges and Unlocking Potential

Piotr Mazurek
pima@emendo.com
+45 21 77 40 69
Scientific Senior Consultant
PhD Polymer Science

Hanne Everland
he@emendo.com
+45 93 98 08 64
Vice President
PhD Polymer Science

emendo
Research & Development

AGENDA

Emendo
Short intro

Bioplastics
Recap & relevance for MedTech

Market
Essential insights

Challenges
Selected common challenges

Take-aways

Emendo Consulting Group

We empower people and foster the good story

Established in 2006

90% of our business is within pharma and manufacturing industries. We have 5 offices across Denmark, Germany, and the US. Our total staff is +210 people, mainly engineers and scientists.

- DIGITAL
- ENGINEERING
- IMPLEMENTATION
- IMPROVEMENT
- PLM SOLUTIONS
- PROJECT CONSULTING
- PROJECT SERVICES
- R&D
- USA SERVICES

READ MORE BY VISITING WWW.EMENDO.COM

EMENDO R&D SCIENTIFIC SERVICES

We can assist in all product development phases with a sustainable edge

Relevant fields of expertise within product sustainability

PROJECT MANAGEMENT				
MATURITY ASSESSMENT	MATERIALS	DESIGN	MANUFACTURING	LOGISTICS
Corporate level assessment	Low-footprint materials	Eco-design	Renewable electricity	Transport packaging
Assessment of R&D units	Recycled materials	Design for recycling	Waste identification, VSM	Impact assessment
	BioPlastics	Recyclability guidelines	Waste reduction	Supplier selection
	Carbon capture & utilization	Recyclable packaging	Recycling of waste	BioFuels

CARBON FOOTPRINT LCA SCREENING

COST-BENEFIT ANALYSIS

LEGISLATIVE LANDSCAPE

Requirements for plastics are strict in MedTech

Most used plastics in MedTech

- Devices: PVC, PP, PE, ABS, PC, PU
- Packaging: PE, PP, PET, PVC, PS

Key observation:
Engineers have a strong preference for using materials they already know.
…even if it means overdesigning and overpaying…

Material requirements

- Mechanical properties
- Thermal stability
- Chemical resistance
- Compatibility with sterilization
- Compatibility with reprocessing (reusable devices)

Regulatory & other requirements

- Biocompatibility
- Traceability
- Material availability
- Material consistency
- Stable supply chain
- Need to update authorities about material changes

High material and regulatory **requirements** make material **transitions** time-consuming and **challenging**.
There is a **justified skepticism** towards new ‘exotic’ materials.

MedTech currently focuses on bio-based non-biodegradable plastics

Bio-based

Bio-based Non-biodegradable

Bio-based Biodegradable

Non-biodegradable — Biodegradable

Fossil-based Non-biodegradable

Fossil-based Biodegradable

Fossil-based

Currently, there is **no infrastructure** enabling benefits of **biodegradability** of medical device waste. Therefore, the primary **focus** has been on **bio-based non-biodegradable** plastics.

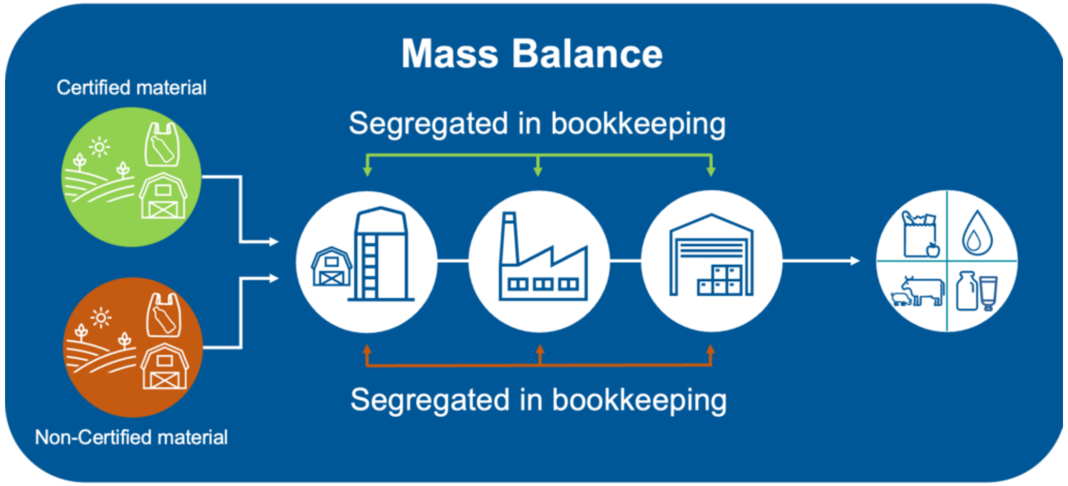
Bio-based Non-biodegradable

Bio-based (physical segregation)

Bio-attributed (mass balance)

ISCC PLUS certifies different chain of custody approaches

ISCC
International Sustainability & Carbon Certification



"Bio-based and fossil-based materials are treated separately in the supply chain and in all manufacturing steps. The final product consists only of certified material."

"Bio-based material is mixed with fossil-based material during the manufacturing processes in the supply chain and separated in bookkeeping. The final material consists of mixed input materials."

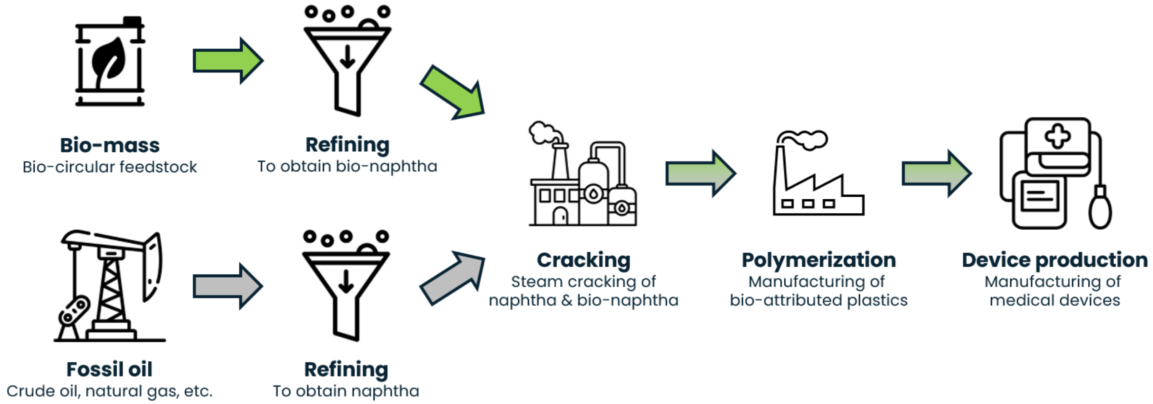
"Mass balance enables the use of bio-based feedstock (biogenic carbon) in intermediates or final products, and subsequent emission savings, where the complexity of the value chains or the level of scale does not yet allow for a full segregated production."

https://www.iscc-system.org/certification/chain-of-custody/
https://docs.european-bioplastics.org/publications/pp/EUBP_PP_Mass_balance_approach_for_the_use_of_biobased_feedstock_for_polymer_production.pdf

Bio-attributed plastics are produced using the mass balance approach

The mass balance principle suggests that your products likely contain some bio-content already now.

Bio-attributed plastics are chemically identical to their fossil-based counterparts.

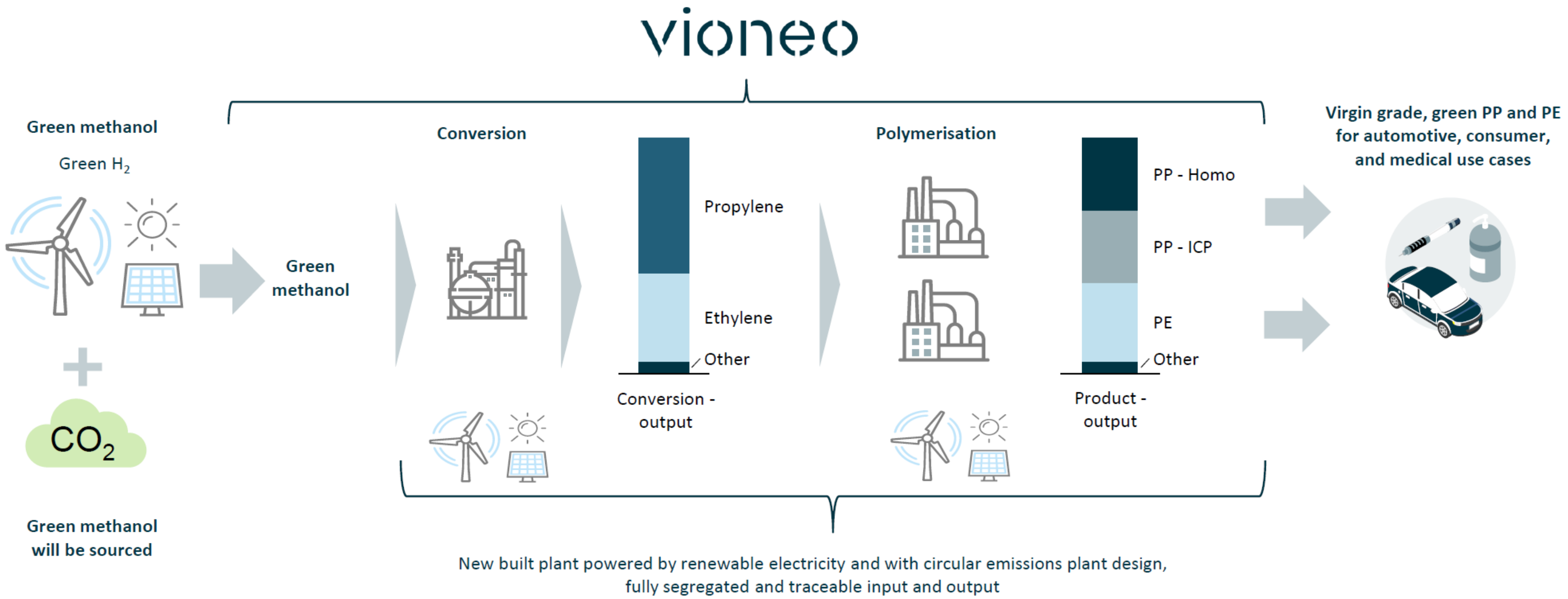


The **mass balance** concept is **not ideal**, but it has a great significance for the **transformation momentum** of the chemical industry.

The mass balance enables a **stepwise** but **continuous increase** of the renewable carbon share.

Additional note:
'Mass balance and free attribution' (MBFA) is an important term that many are not familiar with.

Vioneo – pioneering fossil-free manufacturing of POs from bio-methanol



- Fully **fossil-free PP and PE** produced from **green methanol** containing **only biogenic CO2**, eliminating fossil CO2 from the feedstock
- PP and PE with a market leading fossil reduction, **saving up to 6kg of CO2** per kilogramme of plastic, and with the lowest carbon abatement cost in the market
- **Drop-in**, virgin quality plastics with identical qualities as conventional plastics, requiring no process or product modifications
- Fully **segregated** and **traceable** from input to output, without any use of fossil infrastructure or mixed feedstock

https://vioneo.com/

Selected relevant material suppliers of bio-attributed plastics

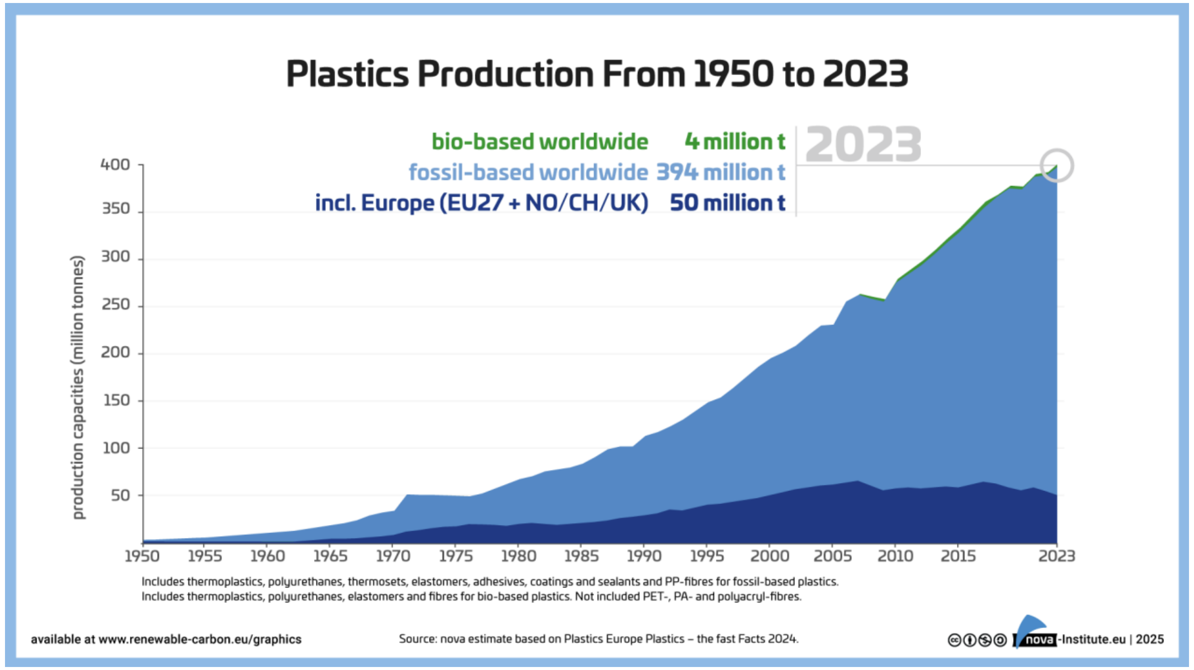
The market of bio-attributed plastics is rapidly developing.

LOTTE CHEMICAL
Japan Polypropylene
AVIENT
versalis
AsahiKASEI
Lubrizol
TRINSEO
INEOS Olefins & Polymers Europe
Techno-UMG Co., Ltd.
EASTMAN
LG Chem
sabic
TEIJIN
covestro
TORAY
kuraray
Mitsubishi Engineering Plastics Corporation
lyondellbasell
INEOS STYROLUTION
DOW
BASF We create chemistry
PRIME POLYMER Our Goal Is To Be Your "Prime Solution Partner."
BOREALIS
SUMITOMO CHEMICAL
MITSUBISHI CHEMICAL
SOLVAY
SYENSQO
SK chemicals
Celanese

Essential information on the market of bio-based plastics

Information extracted from market reports on bio-based polymers generated by the Nova Institute and European Bioplastics.

- In 2024, the total production **volume** of bio-based polymers was **4.2 million tonnes**, which is around **1 % of the total** production volume of fossil-based polymers.
- Bio-based polymers will grow by **13%** per year (**CAGR**) between 2024 and 2029, which is significantly higher than the overall growth of polymers (2–3 %).
- **Asia** and **North America** will **drive** bio-based polymer capacity growth. **Europe's** market share is expected to **decline** by 2029.

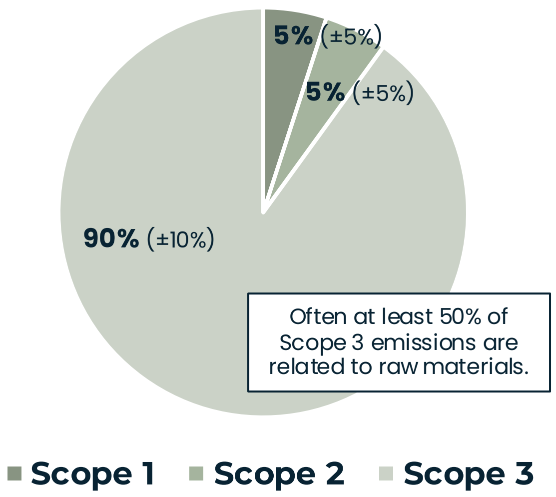


https://www.european-bioplastics.org/market/
https://renewable-carbon.eu/publications/product/bio-based-building-blocks-and-polymers-global-capacities-production-and-trends-2023-2028-short-version/

Substantial carbon footprint benefits vs. premiums

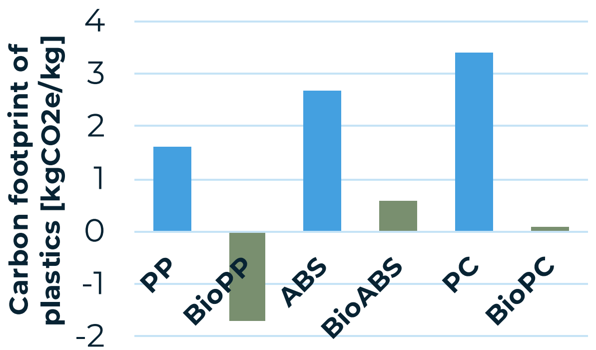
Large portion of emissions comes from raw materials

Scope emissions of a typical MedTech company



Bio-attributed plastics offer substantial carbon footprint benefits

Examples of carbon footprints of plastics



- Data on fossil plastics obtained from *PlasticsEurope* (Eco-profiles set).
- Data on bio-attributed plastics depicts examples of commercially available resins.
- Carbon footprint of bio-attributed plastics were assessed following the -1/+1 approach.

Premiums for bio-attributed plastics

- **Premiums** are usually around **30% - 100%** of base price
- Premiums usually depend on:
  - Bio-attribution level
  - Type of polymer
  - Type of feedstock
- Impact on **COGS**:
  - **Marginal** for expensive devices
  - **Noticeable** for cheaper devices
- Implementation costs:
  - Marginal for 'drop ins'
  - Same as conventional material changes for 'non-drop ins'

https://plasticseurope.org/sustainability/circularity/life-cycle-thinking/eco-profiles-set/

Accounting for biogenic carbon remains a challenge

Brand owners must decide on the approach to ensure consistency of current and future carbon footprint calculations.

0 / 0 approach

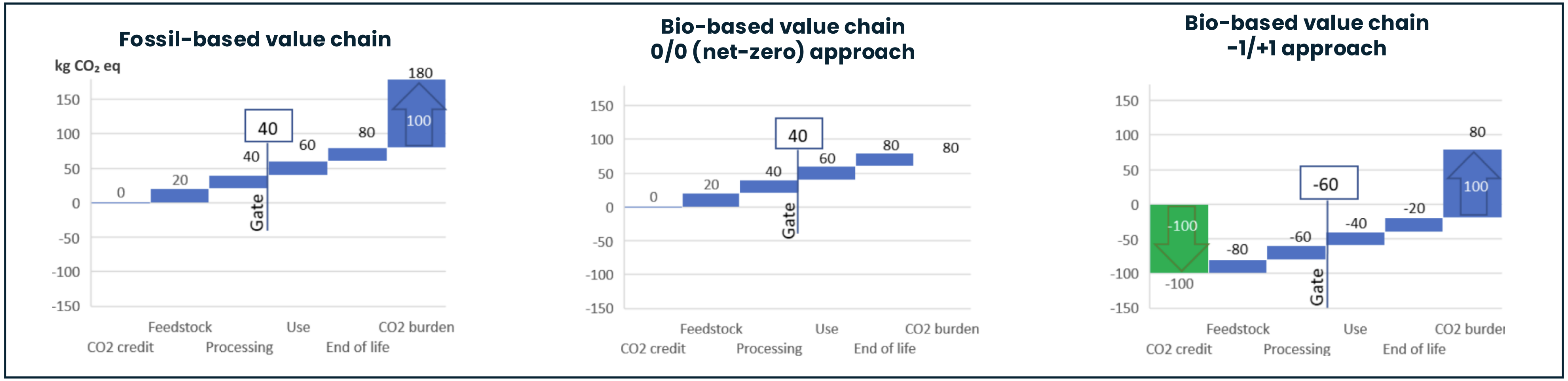
Pros:
- Simplicity in LCA
- Prevents overestimating benefits
- Less risk of misreporting

Cons:
- Underestimates biogenic carbon benefits
- Less incentive for biobased materials
- Lack of transparency (difficult to communicate benefits)

-1 / +1 approach

Pros:
- Reflects the circular nature of biogenic carbon
- Provides clarity on carbon flows
- Incentivizes the use of bio-based material

Cons:
- Complicates LCAs
- Challenging communication
- Misleading assumptions of neutrality



https://renewable-carbon.eu/publications/product/evaluating-lca-approaches-and-methodologies-for-renewable-carbon-sources-report-1-of-3-renewable-carbon-in-lca-guidelines-march-2025-pdf/

Moral dilemma of using the 1st Generation bio-based feedstock

If scaled, the use of 1st Generation feedstock (feedstock that could be used as food) may interfere with food supply chain.

Simplification of two approaches to 1 Gen feedstocks

- **Negative impact** on food supply chain.
- **Costs** of food will **increase** affecting lives of many.

- **Marginal negative impact** on the food industry.
- **Climate change** is the **biggest threat** to food supply stability.
- **1st Gen** feedstocks could be used for **food** production **in crisis** times.

Statements from 3 Danish companies and EU on using plastics with bio-content

Each company is taking a different approaches to bio-based feedstocks

(all statements found online)

LEGO

"Plants from plants are the first LEGO elements made from a plastic produced using sustainably sourced sugarcane."

Ambu

"It is important to us that second-generation feedstock is used because it is not employed for food production."

novo nordisk®

"If using biobased plastic, it must be based on 2nd or 3rd generation feedstock."

EUROPEAN COMMISSION

"…producers should prioritise the use of organic waste and by-products as feedstock…"

https://www.lego.com/en-my/service/help/more_about_us/brick_facts/what-are-plants-made-from-plants-kA009000001dbIsCAA
https://www.ambu.com/endoscopy/single-use-endoscopy/environment
https://www.lyondellbasell.com/49e660/globalassets/sites/2022/hcc2022-presentations/4.-rene-rasmussen---novo-nordisk---sustainable-resins-in-medical-devices.pdf
https://environment.ec.europa.eu/publications/communication-eu-policy-framework-biobased-biodegradable-and-compostable-plastics_en

Take-aways

The medical device sector currently favors **bio-based non-biodegradable** plastics and focuses on **bio-attributed** plastics.

Bio-attributed plastics do **not compromise** patient **safety** or product **performance** and are **compliant** with industry standards.

The medical device sector **accepts** the **mass balance** approach understanding its limitations.

Bio-attributed plastics can be **seamlessly** implemented, bring substantial **carbon footprint benefits**, but come with non-insignificant **premiums**.

The range and bio-attributed plastics is broad, and the global annual **volumes** are **increasing**. The **supply** is **stable**.

Pros and cons of bio-attributed plastics

Current situation in a nutshell: GREAT INTEREST but NO ACTION

Pros

- Substantial **carbon footprint** benefits
- Global **availability** increasing
- **Stable supply** chain
- Wide **range** of available **feedstocks**
- **Decoupling** from **fossil** fuel dependence
- Often **'drop in'** replacements
- Plastics with **properties same** as fossil-based
- **Same recycling** streams as fossil-based
- Good **marketing** potential

Cons

- Non-insignificant **premiums**
- Challenging carbon **footprint calculations**
- Challenging **internal communication**
- Need to transparently communicate **mass balance** externally
- Still **'only' mass balance**

So why is the market stuck?

Premiums to high?
Mass balance being problematic?
Communication too complicated?
Lack of time or clear strategy?

Emendo's areas of expertise within product sustainability

PROJECT MANAGEMENT

MATURITY ASSESSMENT	MATERIALS	DESIGN	MANUFACTURING	LOGISTICS
Corporate level assessment	Low-footprint materials	Eco-design	Renewable electricity	Transport packaging
Assessment of R&D units	Recycled materials	Design for recycling	Waste identification, VSM	Impact assessment
	BioPlastics	Recyclability guidelines	Waste reduction	Supplier selection
	Carbon capture & utilization	Recyclable packaging	Recycling of waste	BioFuels

CARBON FOOTPRINT LCA SCREENING

COST-BENEFIT ANALYSIS

LEGISLATIVE LANDSCAPE

Thank you!

Piotr Mazurek
pima@emendo.com
+45 21 77 40 69
Scientific Senior Consultant
PhD Polymer Science

Hanne Everland
he@emendo.com
+45 93 98 08 64
Vice President
PhD Polymer Science

emendo
Research & Development