Kindeva
DRUG DELIVERY

Switching to sustainable materials for our current devices

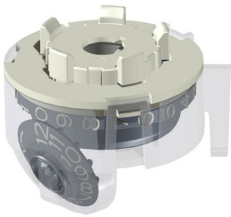
Ed Jackson

Nov 2022

How do we make our current devices more sustainable

Initial Questions and Points to Consider

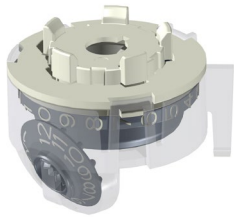
- How do we make this change
  - What does making the current device more sustainable actually mean?
  - How complex will it be to change to sustainable materials?
  - What sustainable material options are available currently or in the future?
  - What is the benefit in making the device more sustainable?
  - Do we change all components or just some of them?
  - Is it best to stay with current material suppliers or source elsewhere?
  - Consider security of supply of the material if you switch?
  - How do you get sustainability certification e.g. ISCC or REDcert?
  - Do you gain certification for the whole supply chain, from material supplier to moulder to product license holder?



How do we make our current devices more sustainable

Initial Questions and Points to Consider

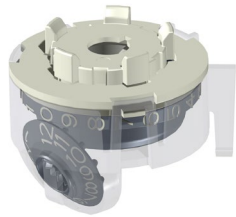
- Technical Points to Consider
  - Understand how material suppliers are moving to sustainable grades e.g. Mass balance, recycling.
  - Assess what sustainable materials are available to make the switch for your device?
  - What can your current material supplier offer?
  - Are there other options from different suppliers?
  - Work with your suppliers to confirm if it is the same material. If so, this could reduce the work required?
  - Is the new material giving the same manufacturing process and technical performance?



How do we make our current devices more sustainable

Initial Questions and Points to Consider

- Technical Points to Consider
  - How can the material supplier support you with the switch with respect to technical and regulatory aspects?
    - What testing have they done?
    - What is their certification?
    - Availability of equivalence data and bio compatibility to support your assessment ?
    - Regulatory impact for the material – is this the same material and DMF as the standard grade?
  - Work with your moulder or CDMO to agree level of work required to implement this change.
    - Is full qualification really required?

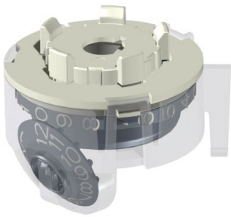


How do we make our current devices more sustainable

Initial Questions and Points to Consider

- Cost and Time Implication
  - How much will it cost ? Who will pay for this?
  - How long will it take?

- Regulatory Impact
  - How is the material supplier documenting this change from a Reg perspective?
  - How will this change impact any device requalification and regulatory impact to approve the change?
  - Is there any clear guidance on how to support such a change?

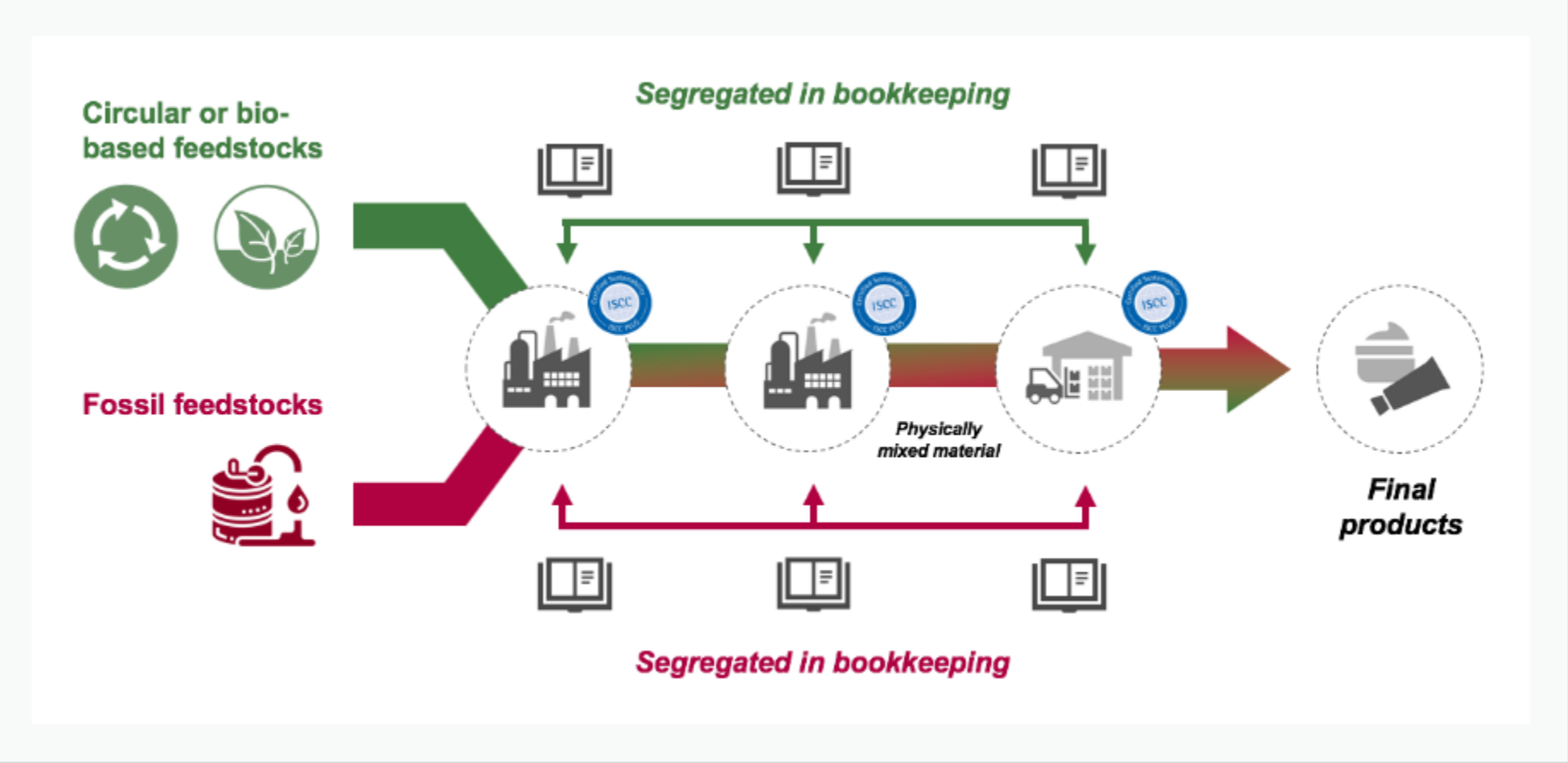


How do we make our current devices and future more sustainable

- Thinking ahead – Our second sustainability roundtable discussion in early 2023.
  - How do we design next generation devices to be more sustainable?
  - Can we reuse a device?
  - Can we recycle?

Mass Balance

- Currently seems to be the main strategy among material suppliers certainly for the medical industry.



https://www.iscc-system.org/about/circular-economy/mass-balance-approach/

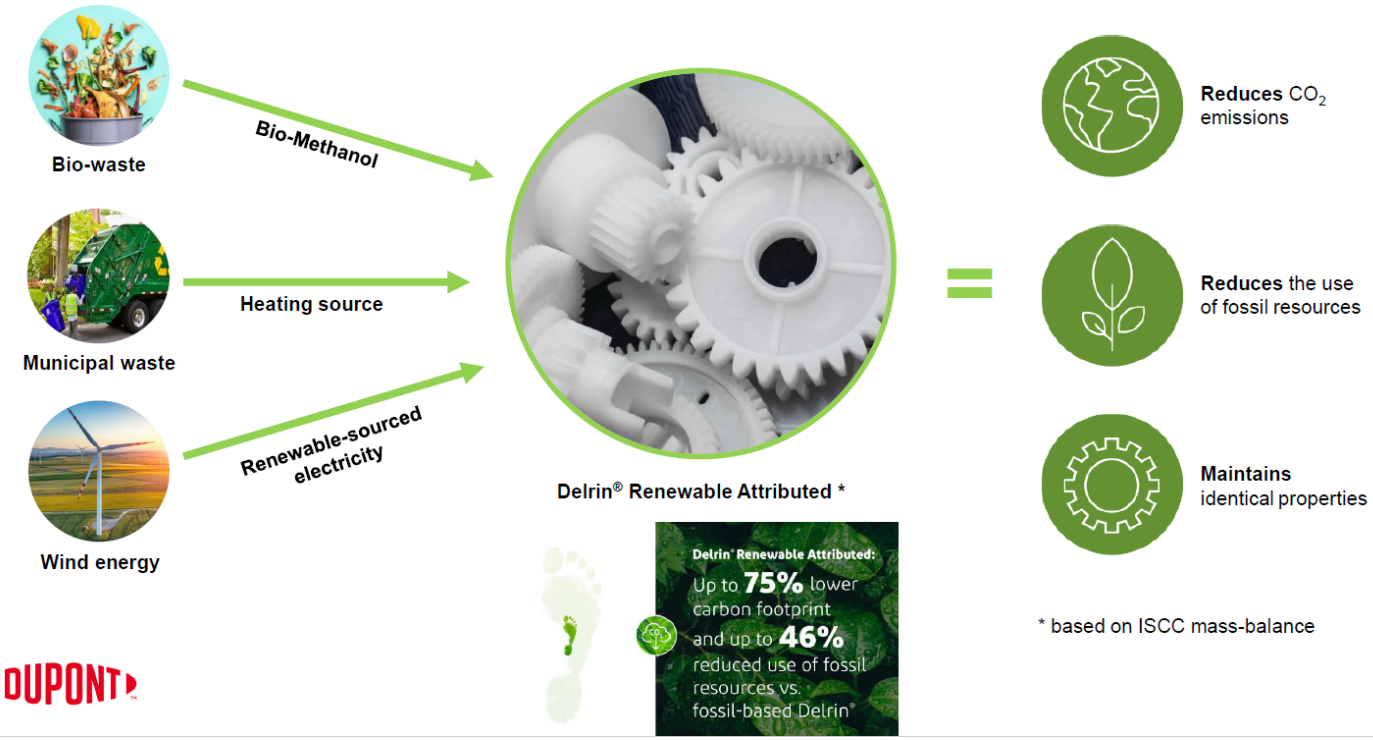
Next Roundtable Discussion in 2023

- Both DuPont and Celanese kindly supplied the following slides overviewing their strategy to moving to sustainable grade.
- Both companies will join us for our next discussion in early 2023 to provide more details and answer your questions.

Example of Sustainability Switch - DuPont Delrin

Example of Sustainability Switch - DuPont Delrin®

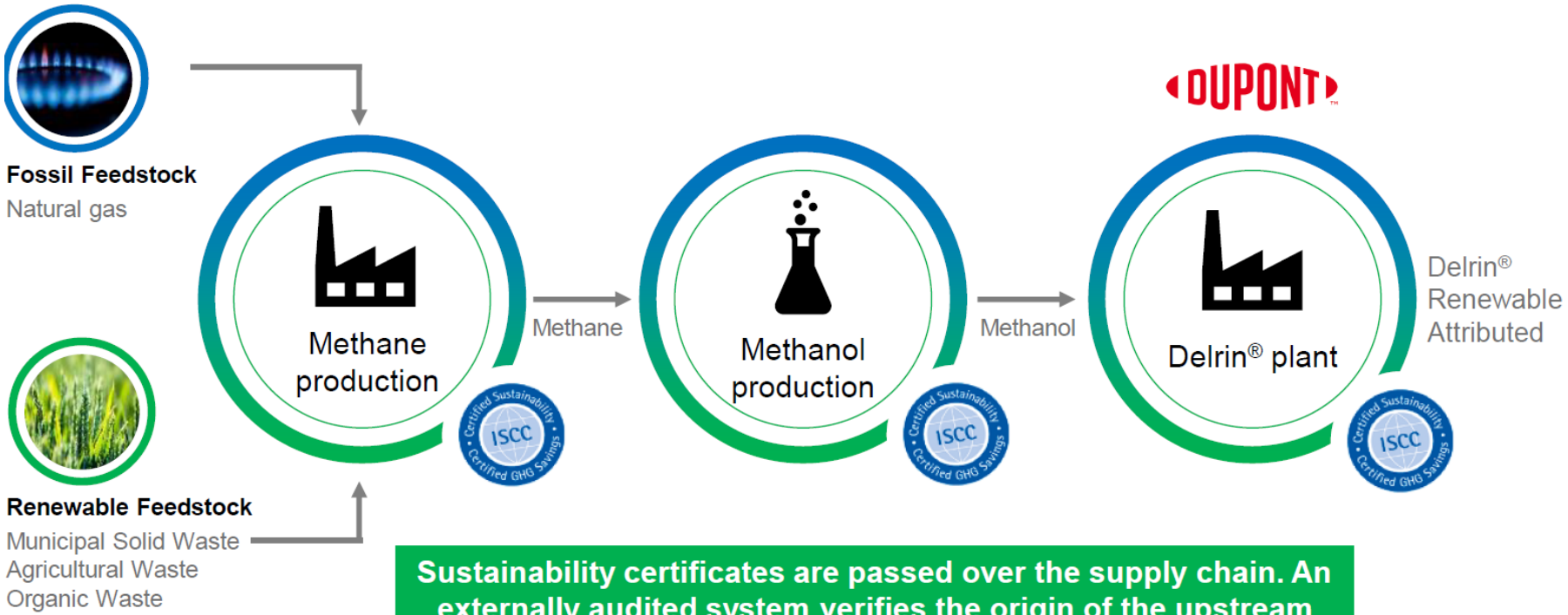
Delrin® Renewable Attributed – Breakthrough of Sustainability



Renewable, high crystalline acetal resin produced from biomass waste, showing an excellent eco-profile among all engineering polymers. 100% of the base polymer is renewable, based on mass balance

Example of Sustainability Switch - DuPont Delrin ®

From biomass waste to Delrin® Renewable Attributed



Sustainability certificates are passed over the supply chain. An externally audited system verifies the origin of the upstream feedstock and the conversion for all the production steps

DUPONT

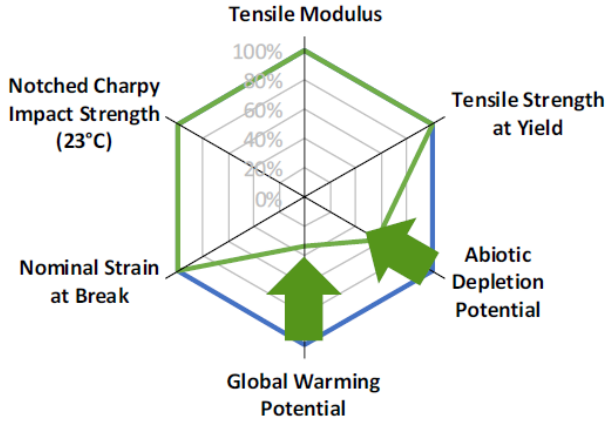
14

CONFIDENTIAL

Example of Sustainability Switch - DuPont Delrin®

Delrin® RASC655 Renewable Attributed

		Delrin® SC655	Delrin® RASC655 Renewable Attributed
Global warming potential	%	100	26
Abiotic Depletion Potential	%	100	54
Melt mass-flow rate	g/10min	15	
Molding shrinkage (parallel / normal)	%	2.0 / 1.9	
Density	kg/m^3	1420	
Melt temperature	°C	178	
Tensile modulus	MPa	3100	
Yield stress	MPa	71	
Yield strain	%	17	
Nominal strain at break	%	30	
Charpy notched impact strength (23°C)	kJ/m^2	9	
Charpy notched impact strength (-30°C)	kJ/m^2	8	



Same processing, mechanical and tribological properties.

Allows fast adoption !

DUPONT

* Manufacturing according to GMP principles, Food contact statements (EU/FDA), Testing against selected parts USP Class VI, Testing against relevant parts ISO 10993, extended change management process.

2

Example of Sustainability Switch - Celanese PBT

Example of Sustainability Switch – Celanese PBT

Source

Celanese
The chemistry inside innovation™

Celanese aims to use waste as the only bio-content material approved for its Celanex® PBT ECO-B.

Our Biogas comes from these 5 sources: *crop waste, water treatment waste, manure, food waste and municipal waste sources.**

Following the Chain of Custody, our 1,4-butanediol suppliers are REDcert² certified. These key global players with sites in every region secure our increasing demand, following the strict quality standards specifications for our PBT manufacturing site

Customer orders a truck load of Celanex® PBT ECO-B

Celanese orders equivalent amount of bio-based 1,4-butanediol

Up to 40% certified biocontent

Our renewable feedstock comes from organic waste **NOT AFFECTING FOOD OR FEED SUPPLIES**. The Chain of Custody is accredited through the mass-balance system certified by REDcert².

Municipal waste | Food waste | Water treatment waste | Crop waste | Livestock waste

Biobased 1,4-butanediol material is certified and shipped to Celanex® PBT manufacturing site.

The bio-based 1,4-butanediol is tracked and accounted for separately from the fossil-based 1,4-butanediol

*These sources are based on renewable materials according to the definition of waste or residue of the Renewable Energy Directive (RED).

External | Celanese Corporation | 11

Example of Sustainability Switch – Celanese PBT

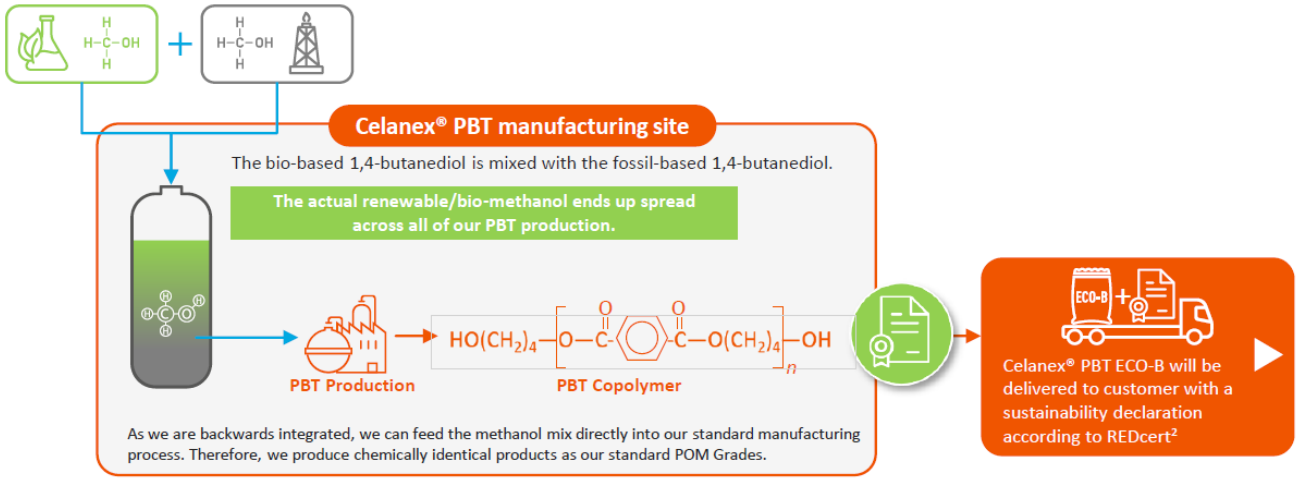
Production & Certifications

Celanese
The chemistry inside innovation™

Drop-in solution

Celanese has risen to the sustainability challenge developing a sustainable polybutylene terephthalate that is chemically identical to our conventional Celanex® PBT with up to 45% of bio-based content via a *mass-balance approach*, certified by REDcert²

REDcert²
This independent company certification audit confirms that we have replaced fossil resources with renewable feedstock. Customer is guaranteed that renewable feedstock is fed into production in equivalent amounts to what is shipped to the customer as Celanex® PBT ECO-B.



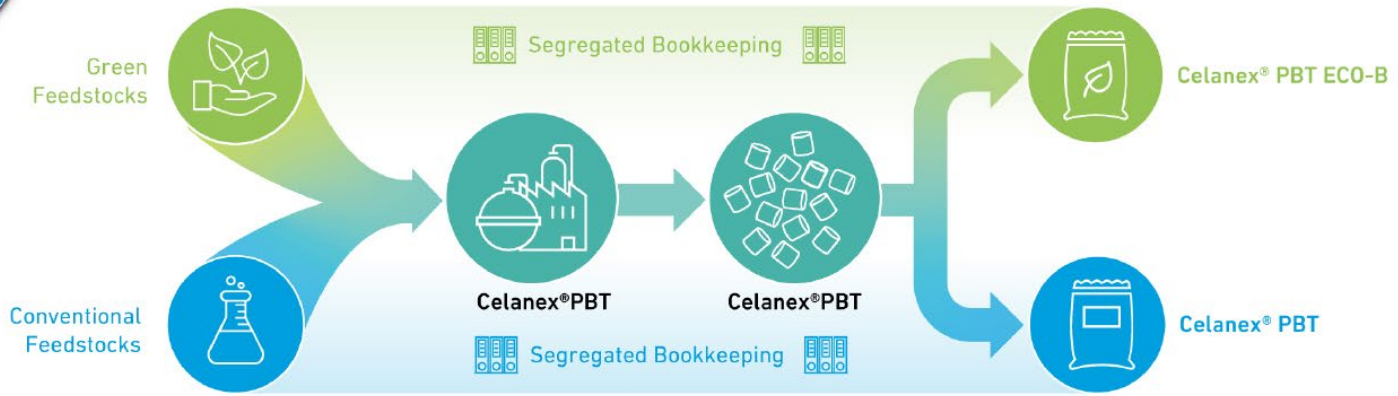
Celanex® PBT ECO-B will be delivered to customer with a sustainability declaration according to REDcert²

We can feed the bio 1,4 Butanediol and mix directly into our standard manufacturing process. This allows Celanese to offer our customers Celanex® PBT ECO-B as the sustainable version of most of our Celanex® PBT grades.

Example of Sustainability Switch – Celanese PBT

Understanding Mass Balance Approach

Celanese
The chemistry inside innovation™



Feedstock:

- Mass balance approach means fossil- and bio-based or recycled feedstocks are mixed in the production but accounted for separately
- Creates demand for non-fossil feedstocks
- Maintains efficiency and emissions benefits of large-scale production technologies

Bookkeeping:

Celanese system to accurately account and track the feedstocks used to produce equivalent amounts of product

- Accounting process and data certified by REDcert², a leading and widely recognized certification body

External | Celanese Corporation | 14

Discussion

Thank You

Kindeva
DRUG DELIVERY