



Alternatives Assessment in EU

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13 April 2021

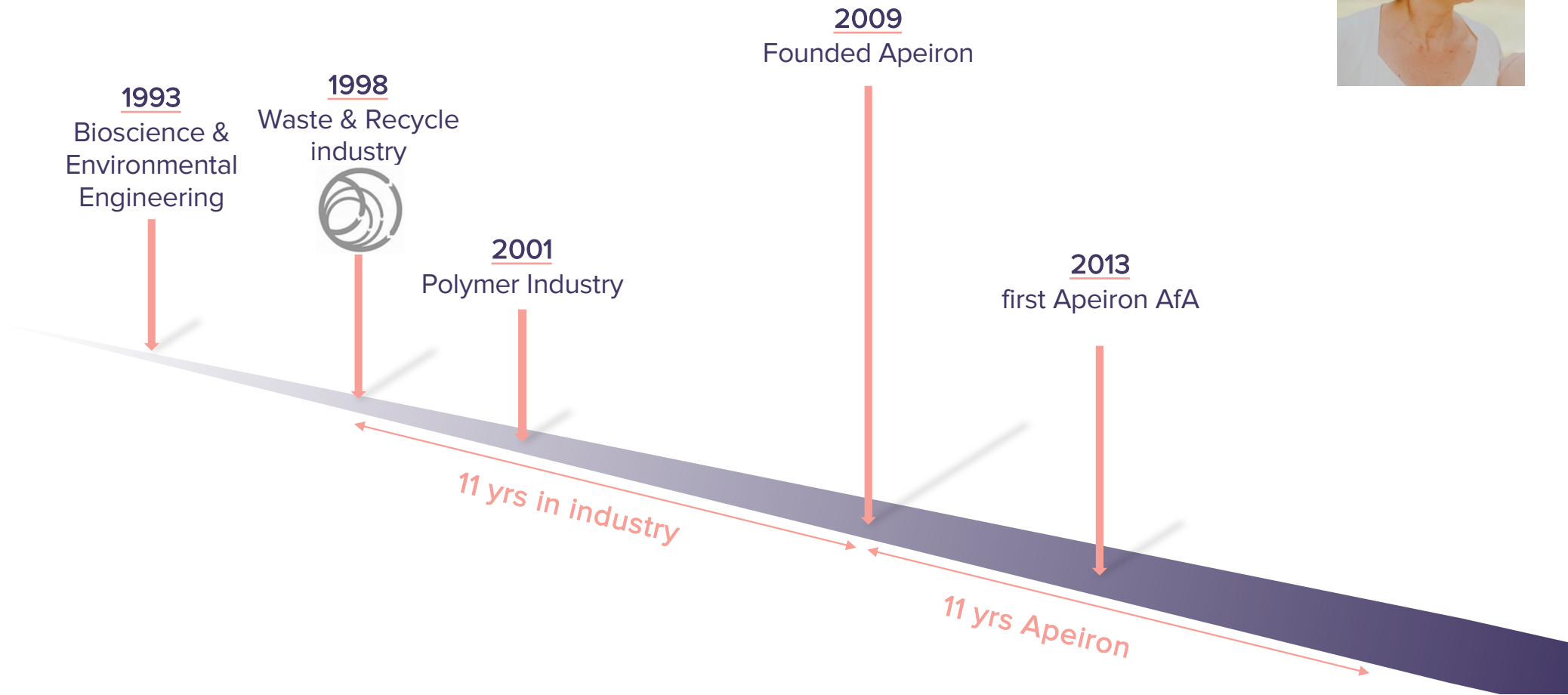
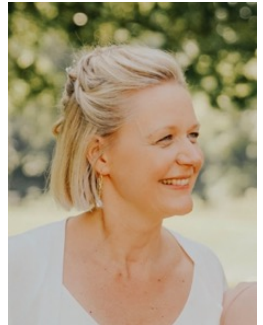


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- The contents are intended to provide a general guide to the subject matter only and should not be treated as a substitute for specific advice concerning individual situations.
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Create **Positive** Impact





since
2009



Passion

to drive
Improvement



Together
with our clients



The Team



Celina



Tine



Laurence



Richard



Katrien



Hiram



Elke



Valérie



Mike



Valentina



Michel



Shari



Laetitia



Eva



Willy



DRIVING THE TRANSITION

Starting from safe use of chemicals,
Apeiron guides its clients to
sustainable, future proof business operations.



Stepping up from “LINEAR-IN-A-CIRCLE” to “CIRCULAR”



OR



Linear-in-a-circle
= Bilateral system

Circular
= Ecosystem



Where Innovation & Regulation meet

Chemicals are used everywhere
and that is OK, they bring health & prosperity for society

- Surfactant in *in vitro* diagnostics used to diagnose diseases, e.g. Covid-19
- Solvent used in the production of promising innovative cancer treatment
- UV filters in sunscreen to protect us from skin cancer
- Adsorbing agents used in sanitary towels and tampons
- Polymers used in tents to make them light and weather resistant in the mountains
- Surface treatment that ensures that the ballustrade of your 6th floor apartment is robust

but ... we need to maximally avoid Substances of (Very High) Concern



Where Innovation & Regulation meet

Apeiron assesses its client's substance portfolio for improvement opportunities.
We identify where they can achieve the biggest impact with the available resources

Apeiron developed a standard methodology with Priority setting for

Proactive Alternatives Assessment

This includes assessment of

- Toxicity & Risk
- Climate
- Circularity
- Resource depletion

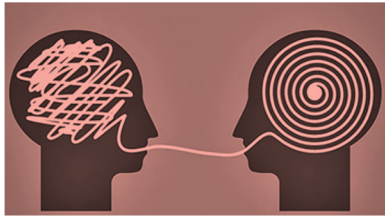
For the entire life cycle of the substances

- ensuring the alternative does not create a new risk up-or downstream = regrettable substitution
- e.g. Alternatives for Cr(VI) based on Cr(III)sulfate, which is produced starting from Cr(VI)



Alternatives Assessment (AA)

Reactive AA	Proactive AA
Result of <u>legal obligation</u> , Fits in a regulatory process e.g. REACH	Fits in <u>voluntary</u> effort
Pushes <u>all</u> companies to improvement	Works only with <u>fronrunners</u> , while others lag behind
Demonstrates there is no suitable alternative = negative assessment Obliges to make commitment via <u>substitution plan</u>	Looks open mindedly for future opportunities = positive assessment
Has to stand <u>external scrutiny</u>	<u>Internal</u> process
<u>Time</u> for substitution = minimum needed Time is intrinsic element of AA & of decision by authorities	<u>Time</u> as needed to develop the most sustainable alternative
Time pressure = Risk for <u>regrettable substitution</u> Unless sufficient time is granted ! (see examples later)	Most <u>optimal</u> substitution for <u>industry & society</u> (see examples later)



Learning

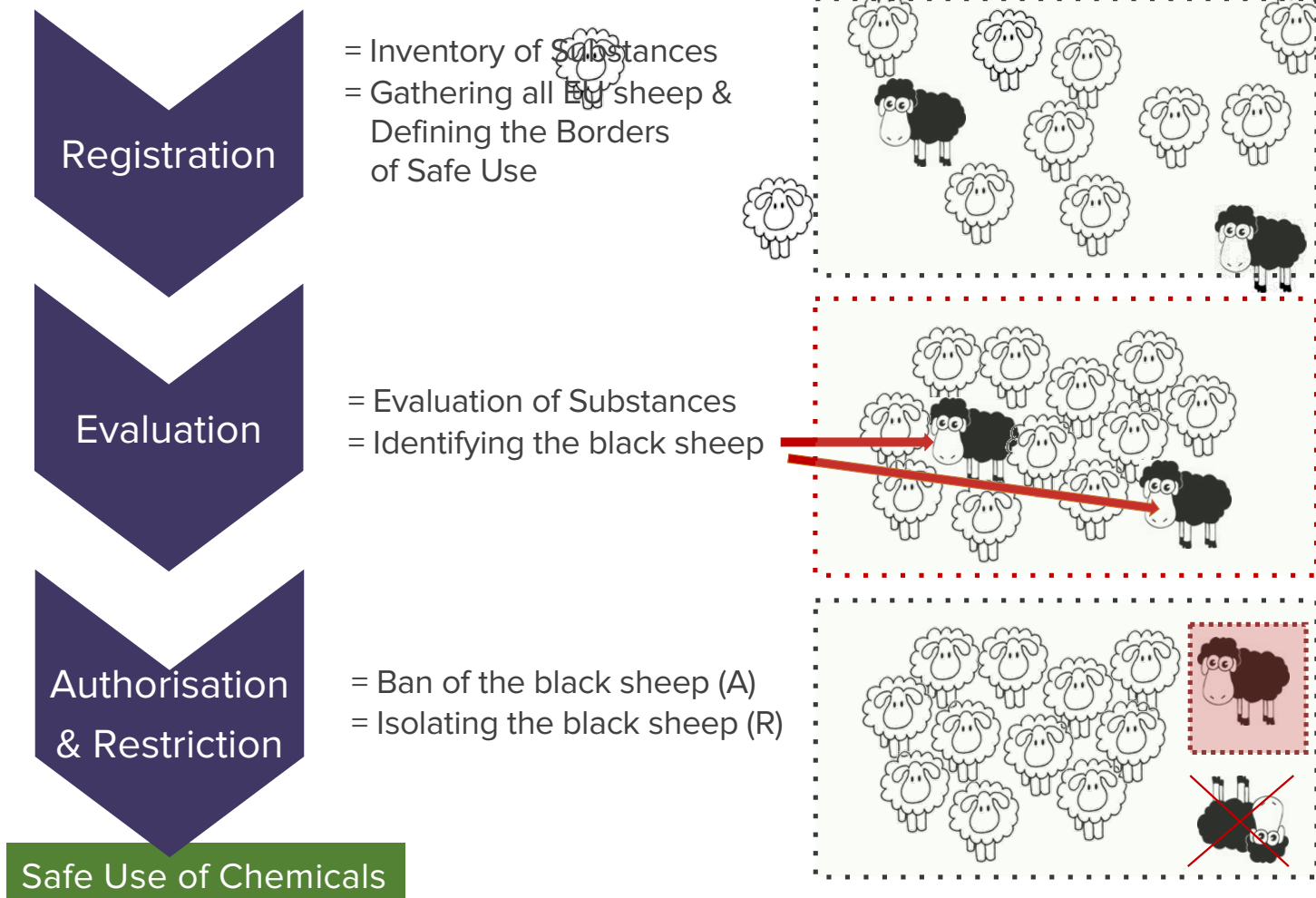
Proactive Alternatives Assessment
is more effective to achieve sustainable substitution
but only the frontrunners act
Thus, **to make a difference...**
the world needs regulatory & voluntary actions



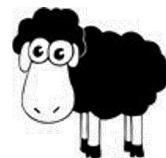
Alternatives Assessment
under
REACH & Beyond

“Look for the alternative”





What is an SVHC?



Carcinogen to humans



Mutagen to humans
(DNA damage)



Reprotoxic to humans
(fertility and/or
development of foetus)



PBT / vPvB



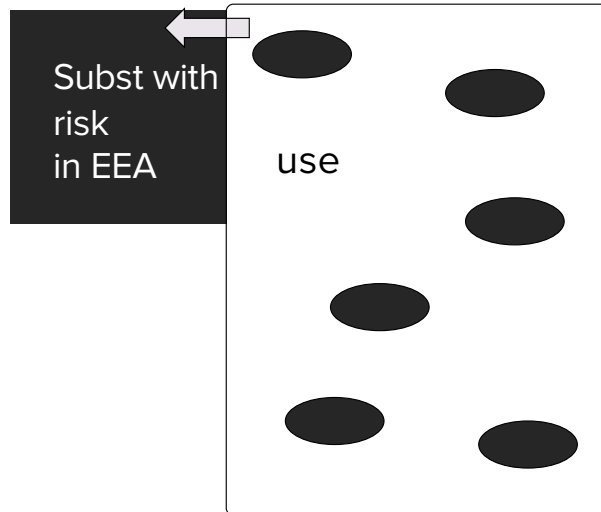
Equivalent concern

Edocrine disruptors
Respiratory sensitizers
PMT/vPvM



Restriction

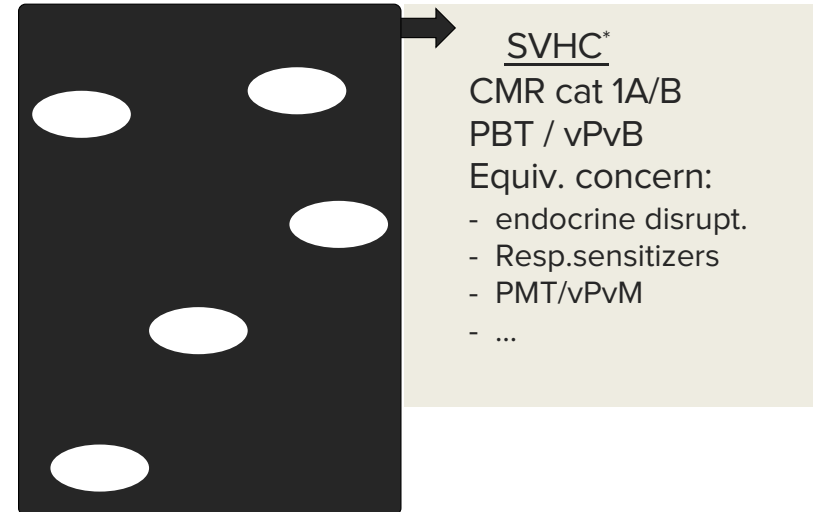
Annex XVII



Allowance to use,
under restricted conditions
→ Forbidden zones

Authorisation

Annex XIV

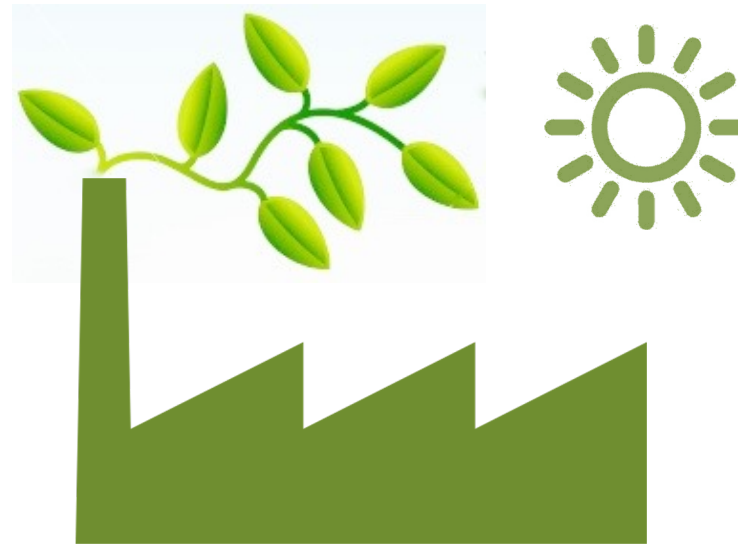


Prohibited to use,
unless authorisation granted
→ Islands of allowed use
→ Time Limited

*SVHC = Substances of Very High Concern



Application
for
Authorisation



1. Risks properly controlled
 2. SVHCs progressively replaced
- = AIM AUTHORISATION (art 55)

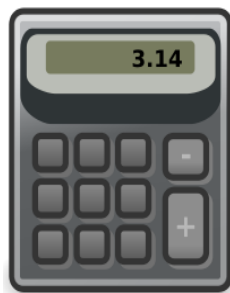




Exposure & emissions are minimized
Opportunities to further reduce emissions

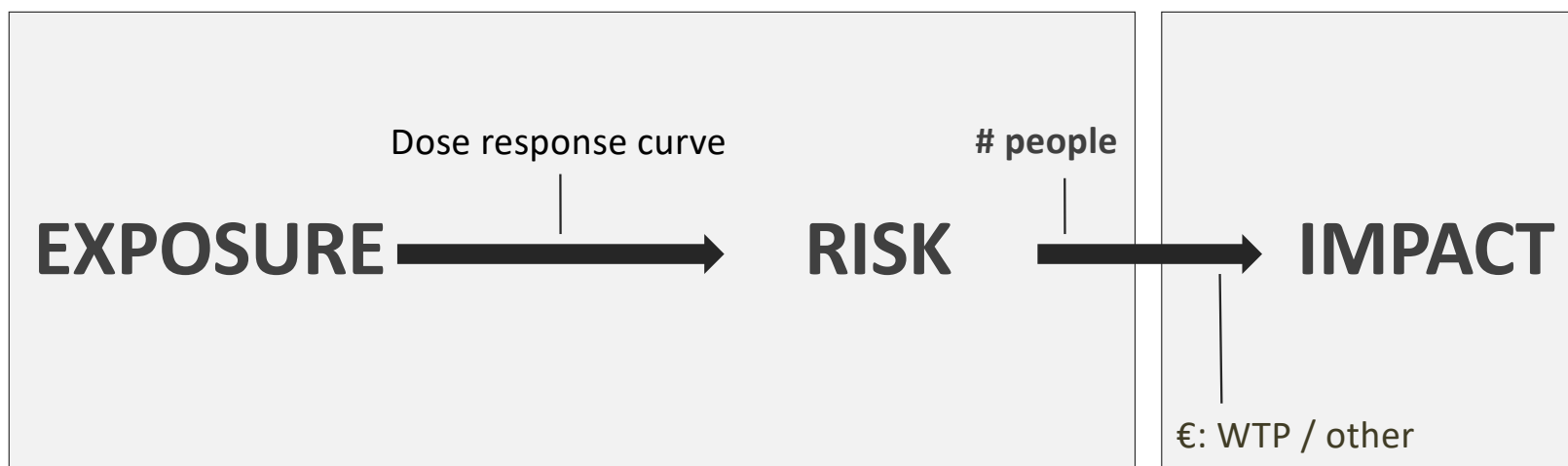


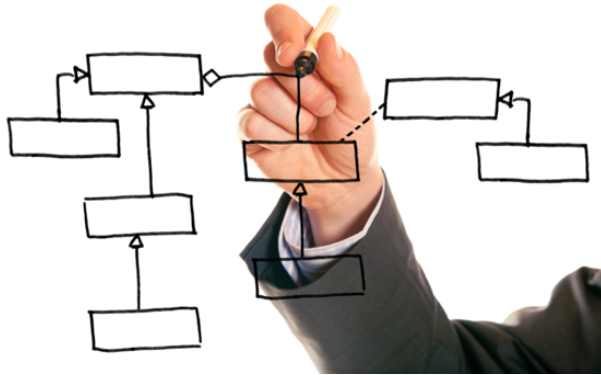
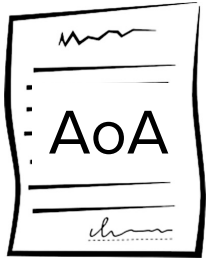
Description R&D history
Opportunities to find even better solutions



Balance of impacts
“use -applied-for” vs “non-use”

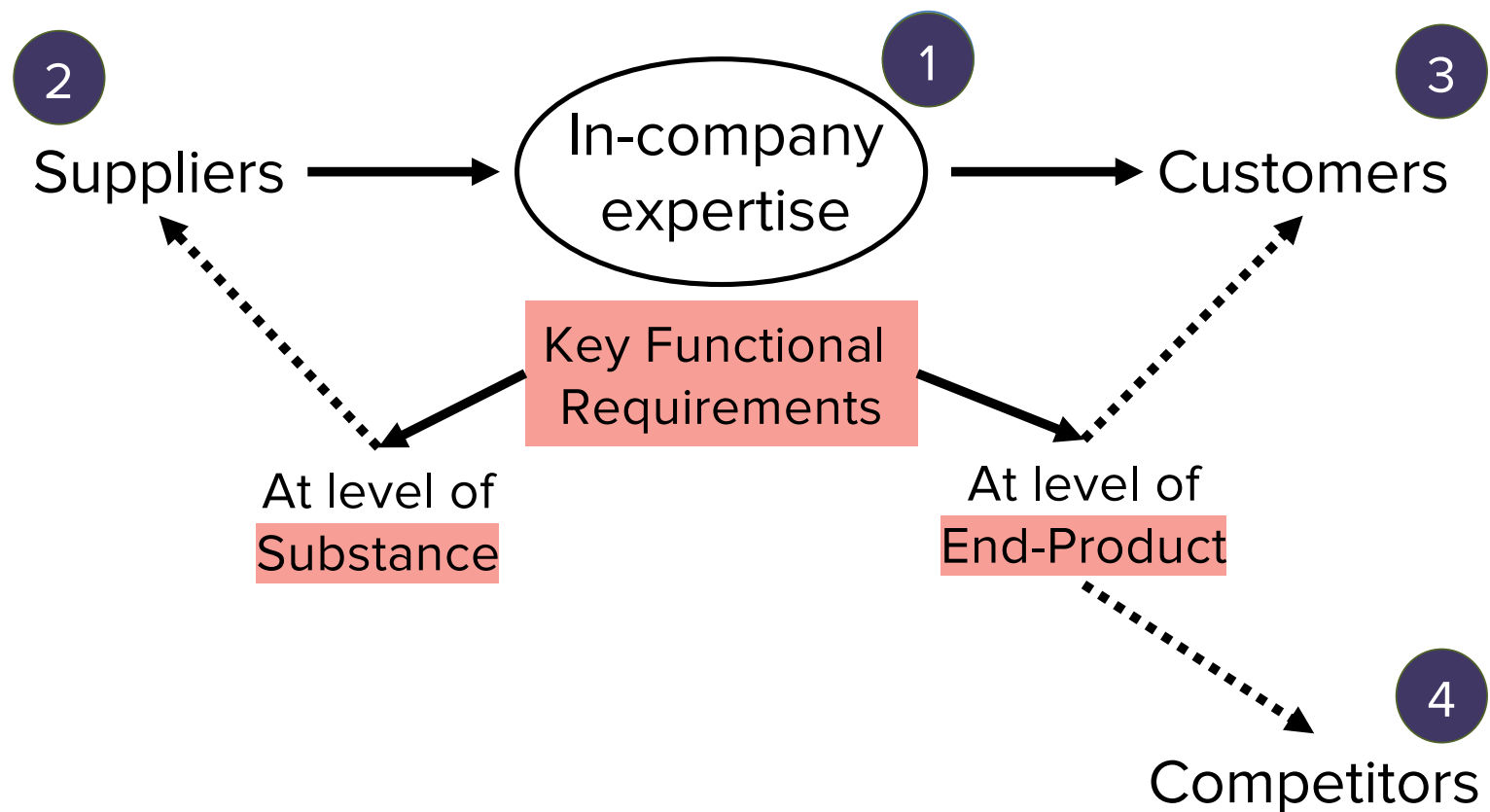






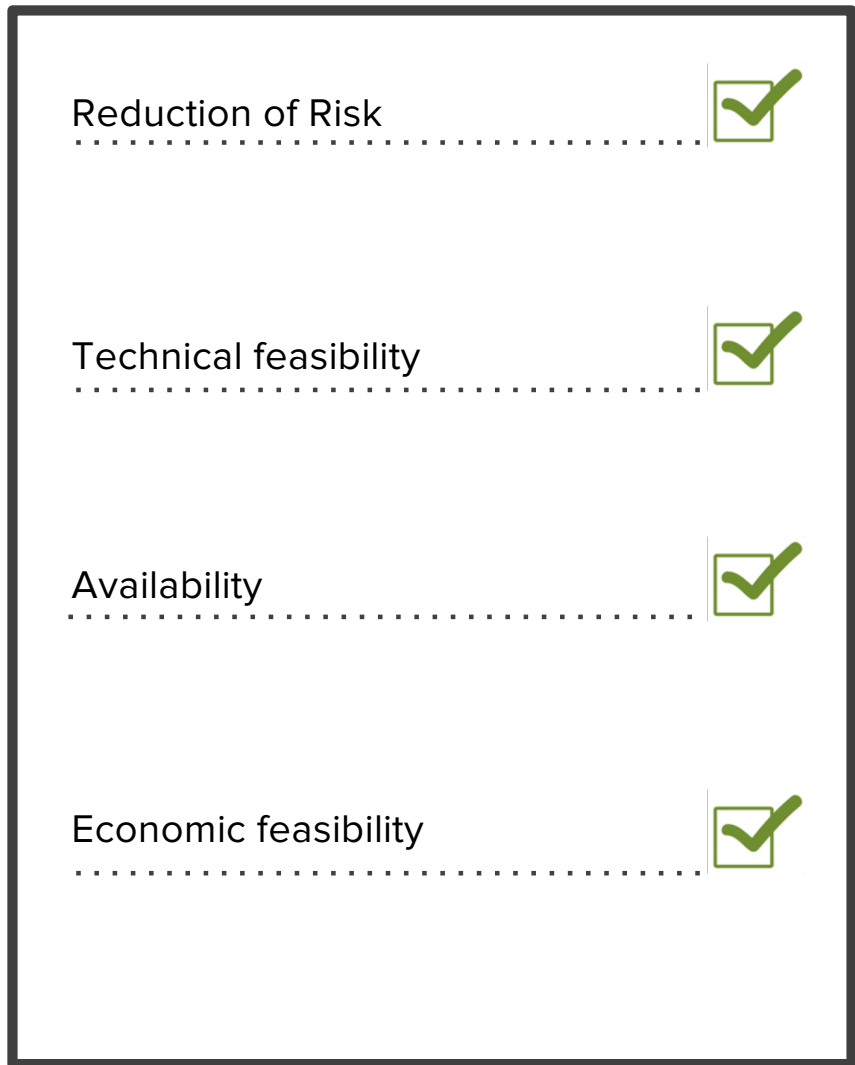
Key Functional Requirements





- 5 Google
- 6 Dbases (WIPO Green, Market Place, Chemycal,...)
- 7 Green Chem. Conferences





the AoA is company and business dependent



Comparative Risk Assessment

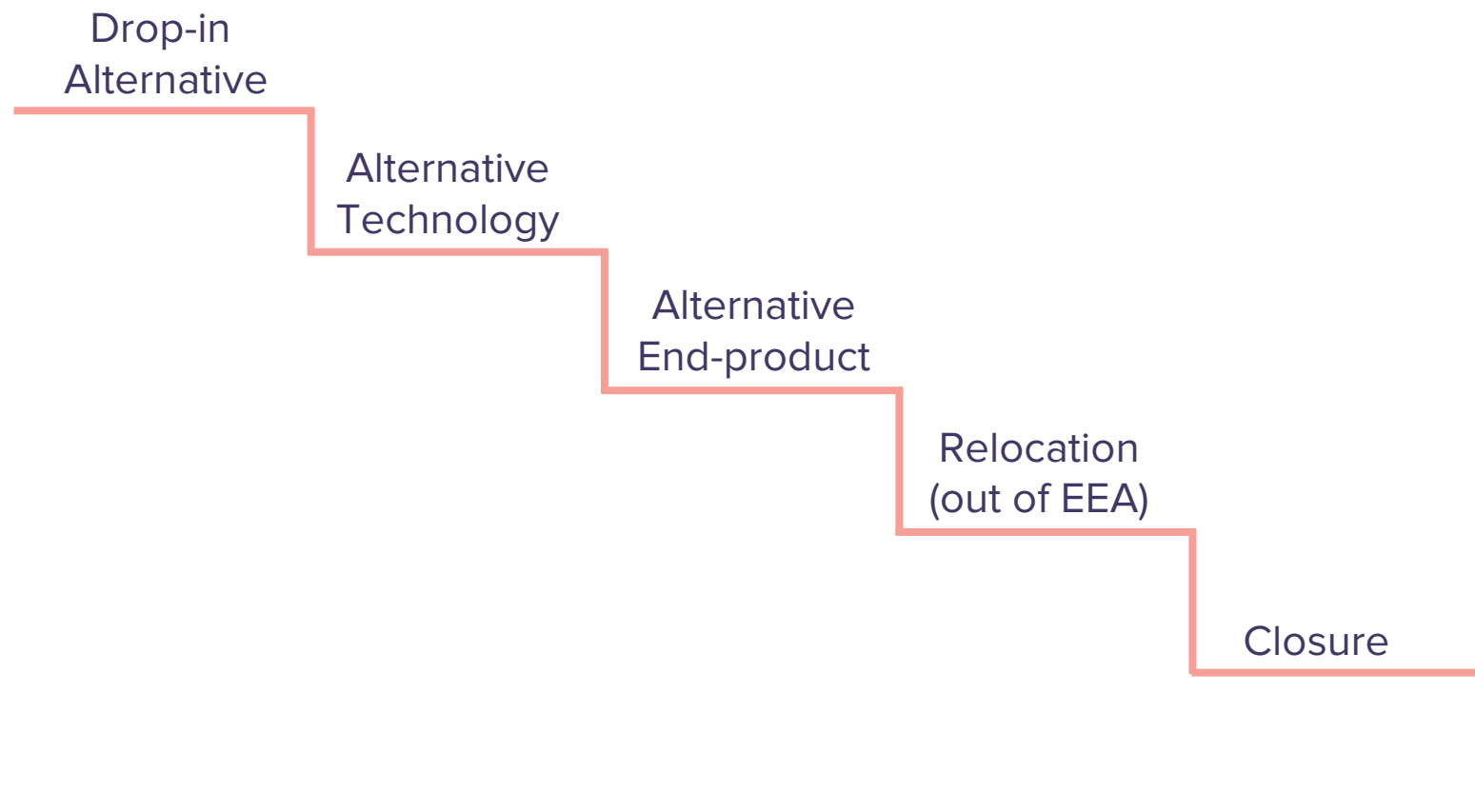
on Toxicity & HH/ENV Health Risk
on Climate
on Circularity
on Resource Depletion

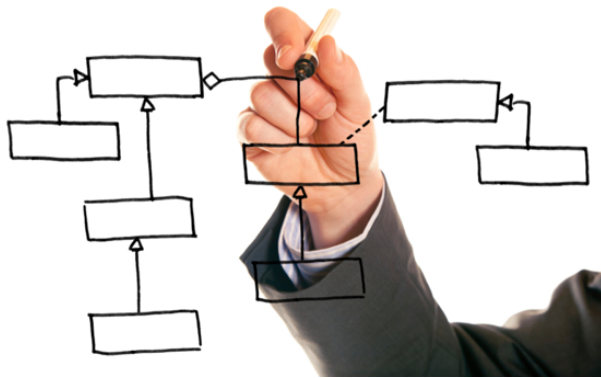
for the entire life cycle
→ Avoiding regrettable substitution

Reduction of Risk	✓
Technical feasibility	✓
Availability	✓
Economic feasibility	✓

Potential Alternative				
✓	✓	✗	✗	✓
1	2	3	4	5







Applied for Use Scenario
with development plan
&
Non Use Scenario

the AoA defines the future business strategy



Authorisation is not avoiding substitution

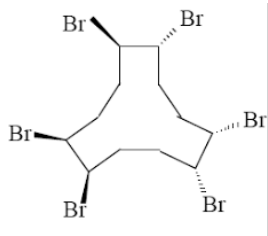
Authorisation is a plan towards substitution,
while emissions & exposure (to workers & man-via-env) are
continuously improved/mimimized



What can we learn
from Example Cases?

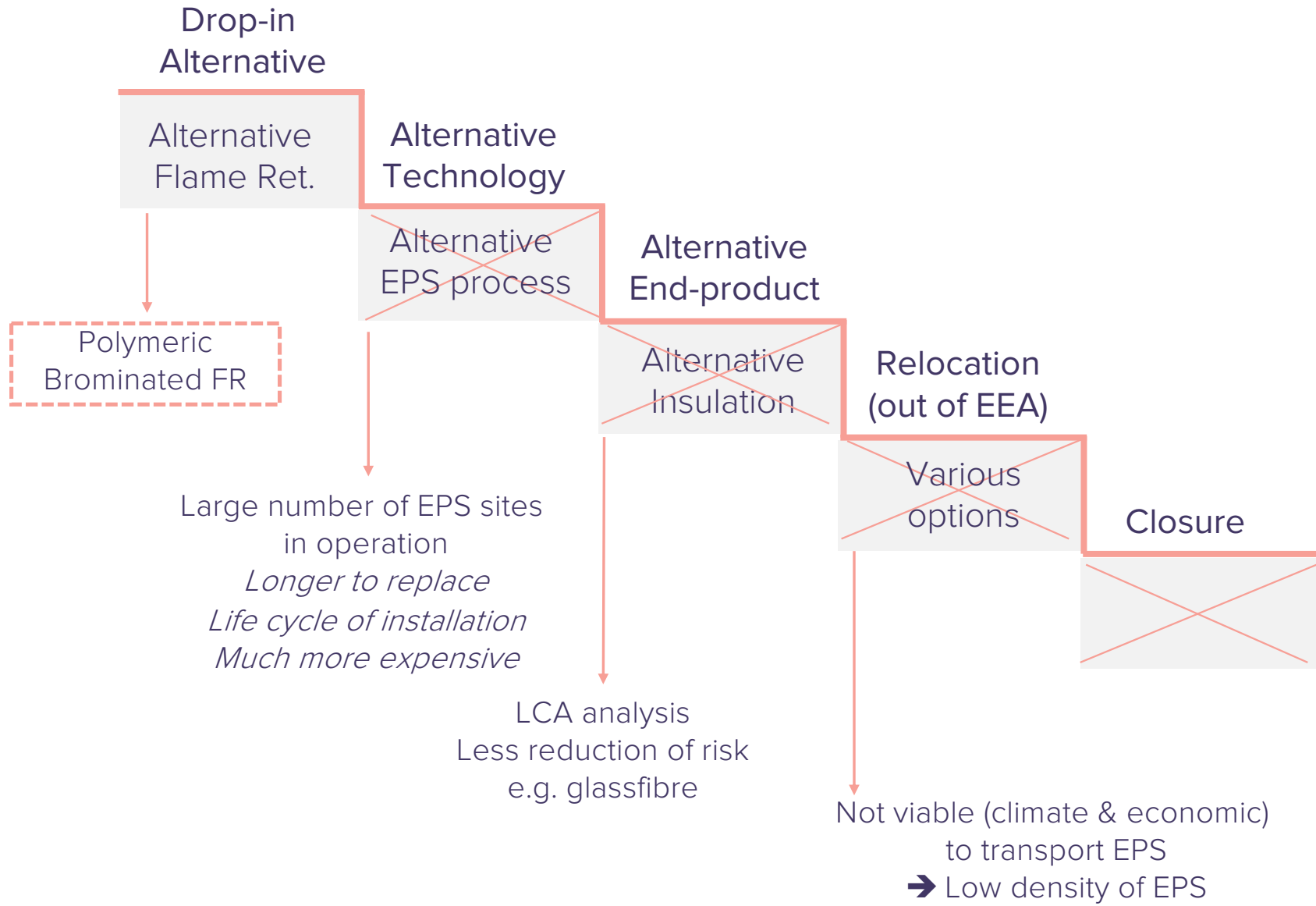


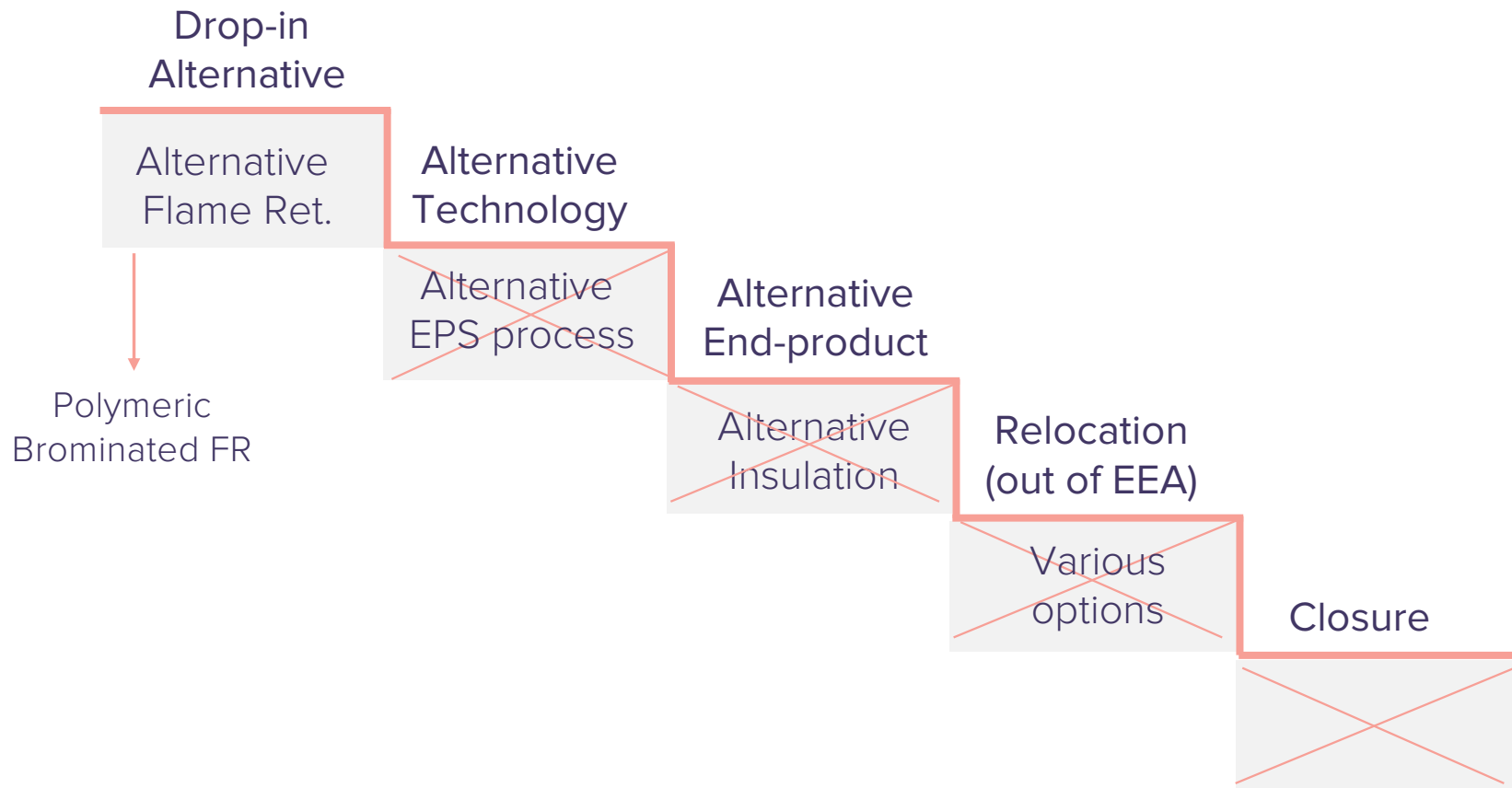
HBCDD



- Flame retardant for EPS and XPS
- PBT properties
- Regulated by POPs convention (2013)
- Included in Annex XIV of REACH (2009) as one of the first substances
- Sunset date for the substance **21/8/2015**

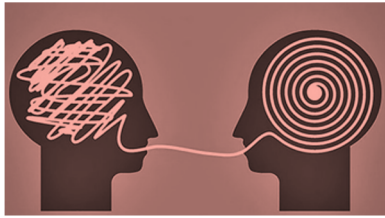






Joint effort between flame retardant suppliers & EPS producers
 Pro-Active research before regulatory scrutiny: 9 years search (2003-2012)
 Authorisation requested for only 2yrs until enough market volume of alternative available
 Authorisation granted for the 2yrs. Substitution in meantime completely implemented.





Learning

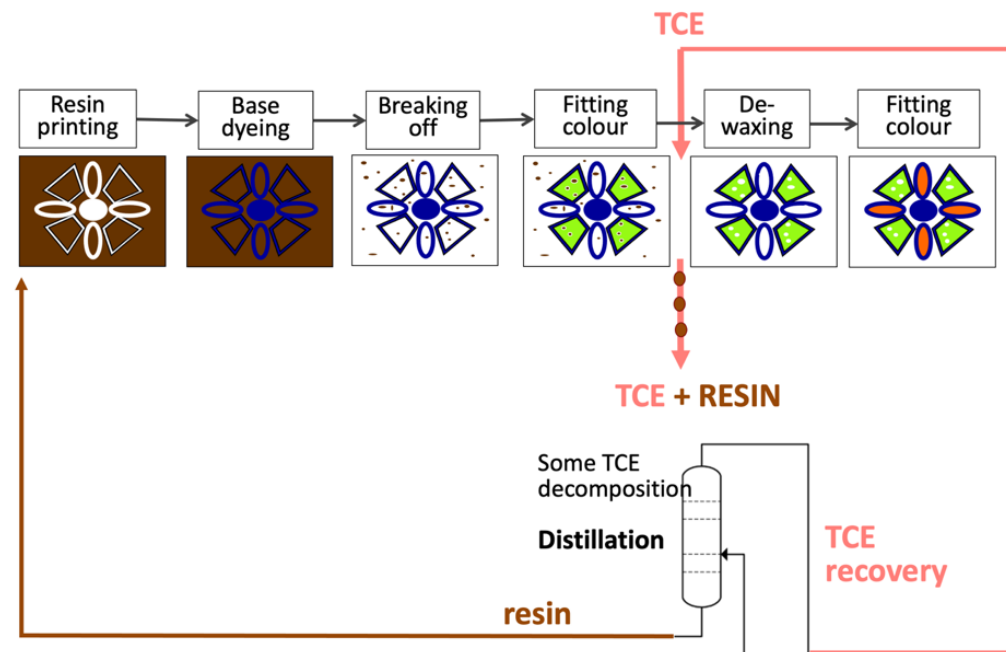
Joined effort between users and producers

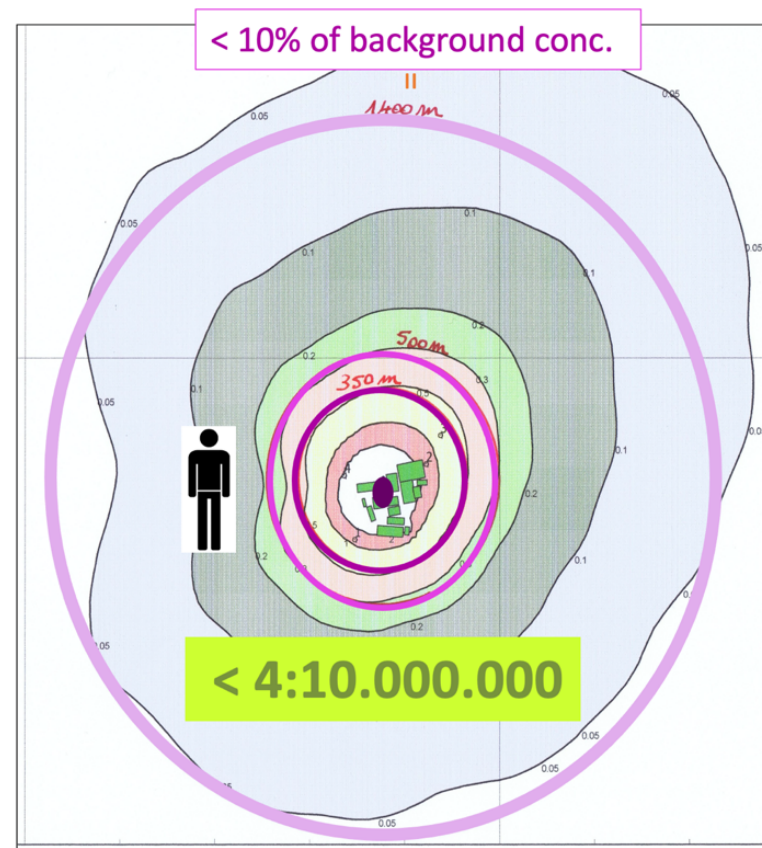
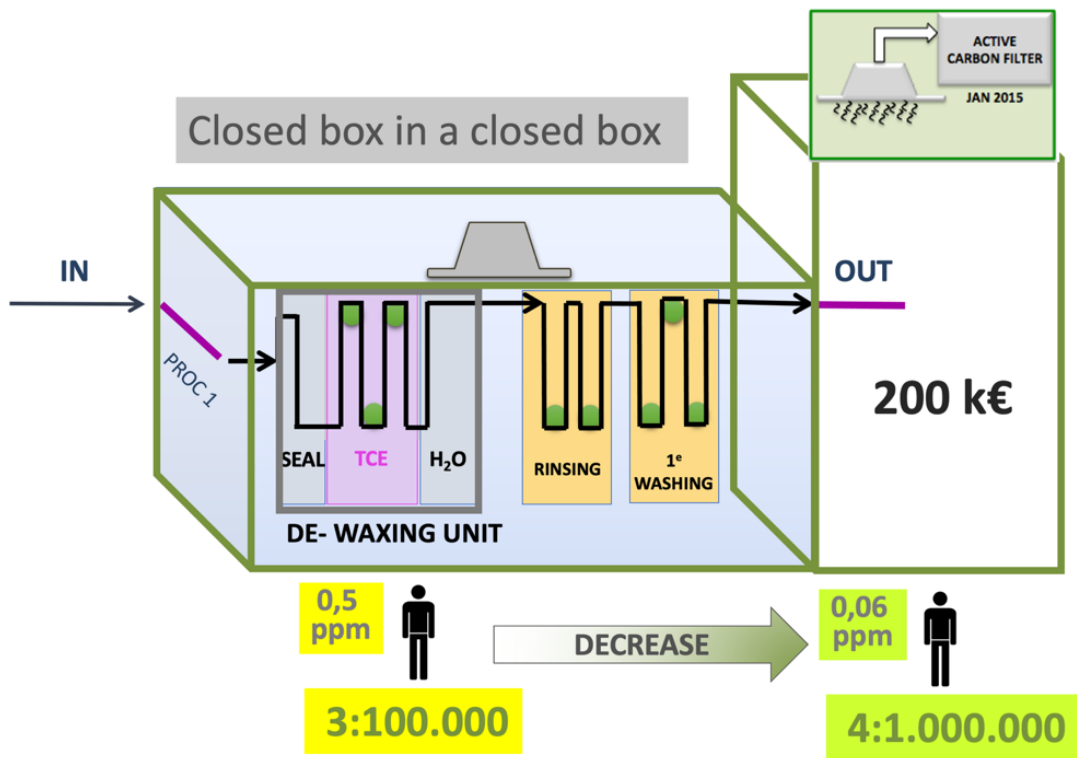
Proactive AA based on inherent property of substance

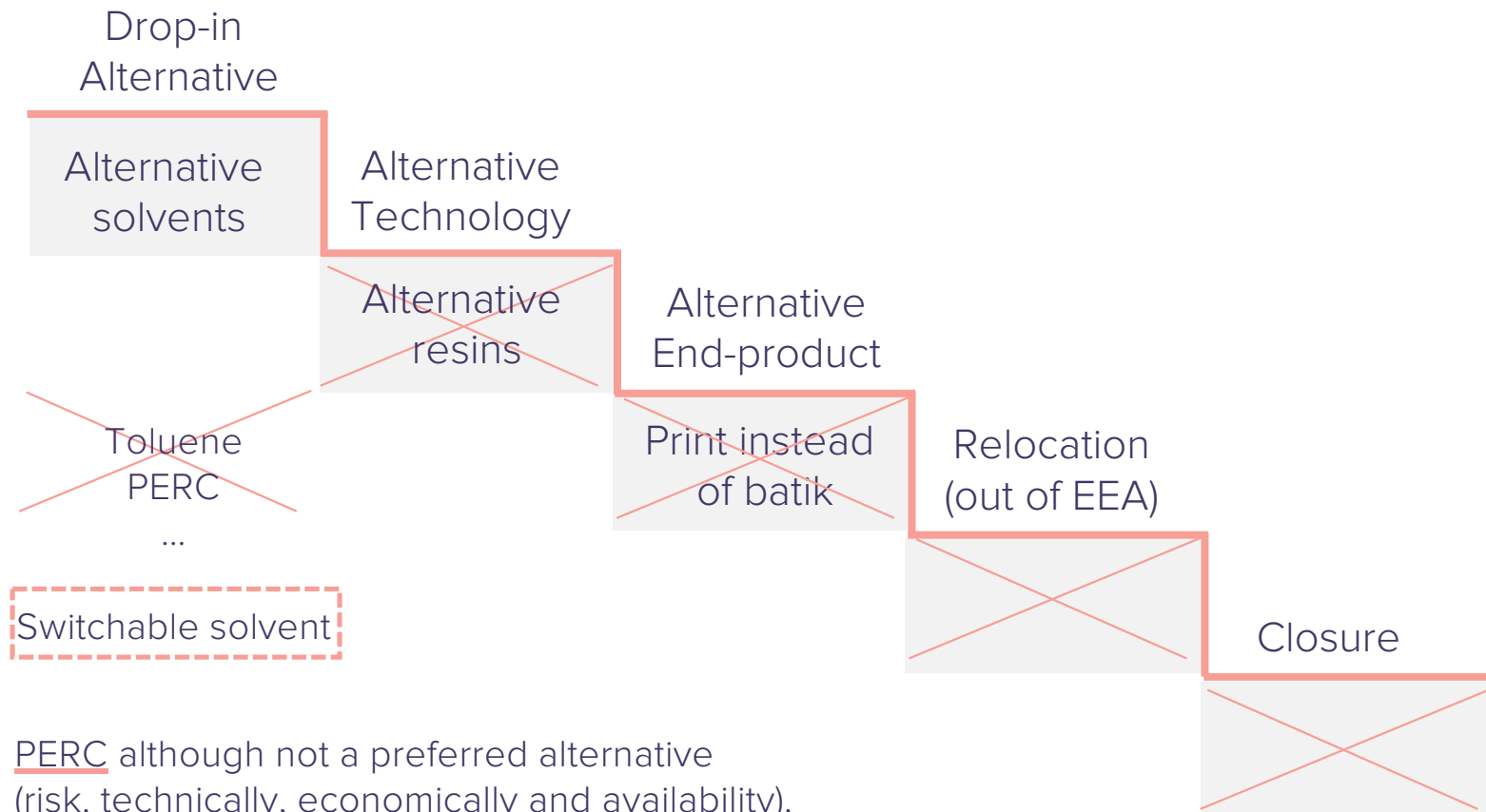
Acting ahead of regulatory requirement is effective



Trichloroethylene







PERC although not a preferred alternative (risk, technically, economically and availability), the quickest and cheapest alternative in case of refused or even short term (4-7yrs) authorisation! Thus, **no or short-term authorisation would have resulted in substitution to PERC = regrettable**

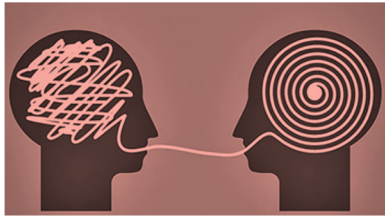
Switchable solvent = innovative, sustainable alternative
 Risk reduction and reduction of energy consumption
 Development time estimated at 12 yrs



Ongoing R&D

- Innovation to sustainable alternatives requires time
- Switchable solvents, but the applicant also continued R&D to other technologies in case switchable solvents would not work out
- Open minded to the best possible solution for applicant & society
- Footnote: AA by downstream versus AA by Manufacturer of the substance
 - Manufacturer typically develops drop-in alternatives only (other solvents)
 - Conflict of interest: manufacturer or supplier high up in the supply chain is not interested in alternatives he cannot produce, e.g. new technologies at downstream user
 - Significant uncertainties in the dossier due to aggregation of information. This leads to shorter authorised periods.
 - Result: No time for development of innovative alternatives. In practice...a significant number of TCE users have in the meantime switched to PERC





Learning

Regulation is a good trigger for substitution.

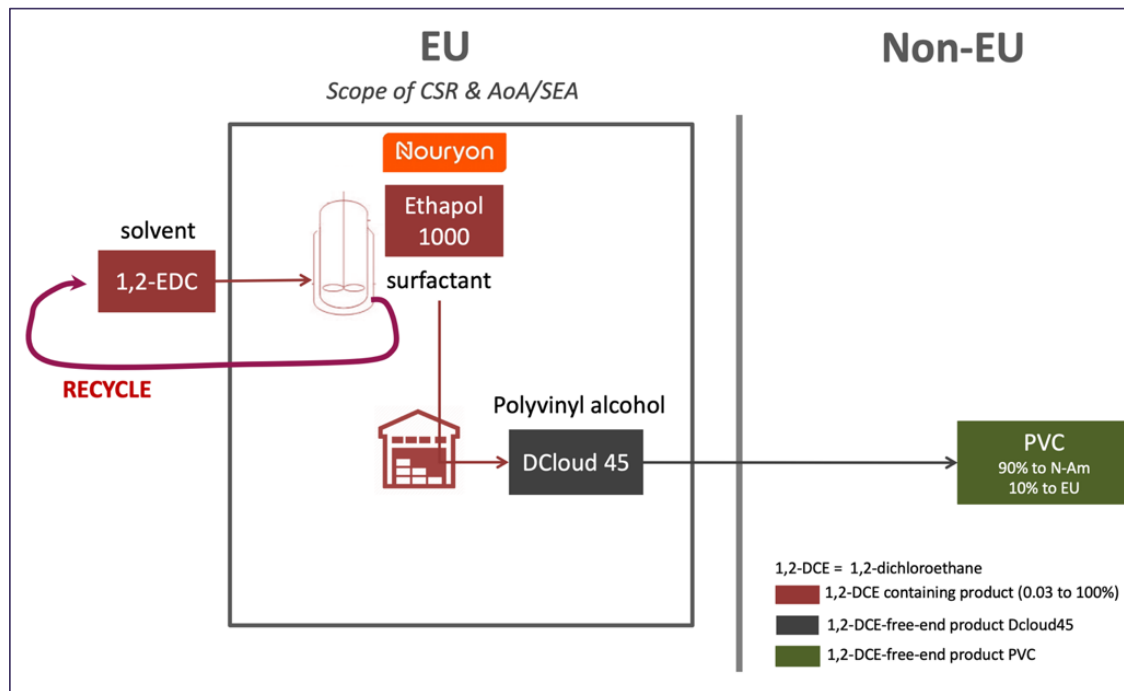
But...Substitution under time pressure
leads to suboptimal substitution or - worst case –
to regrettable substitution.

Substitution from Trichloroethylen to Perchloroethylene is a regrettable substitution.

But unfortunately this is what happened in reality,
because the downstream users were not sufficiently involved in the AA process.



1,2-dichloroethane @ Nouryon



1,2-EDC as solvent in production of surfactant

1,2-EDC is recycled in the process

Surfactant (Ethapol 1000) is used to make DCloud45

DCloud45 is a PVA used in PVC

PVC is used in piping, cable insulation, blood bags, ...

DCloud45 is **the only PVA**

with zero methanol & zero ethanol

Key to US PVC manufacturers for reasons of

(1) explosion safety, and

(2) to comply with US Clean Air Act on

methanol emission reduction obligations



No authorisation (NPV)
ca. 2.980.000€



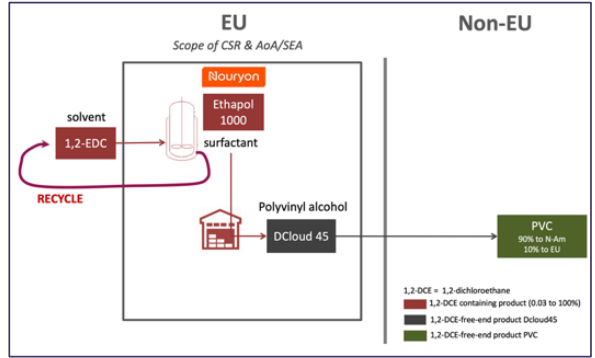
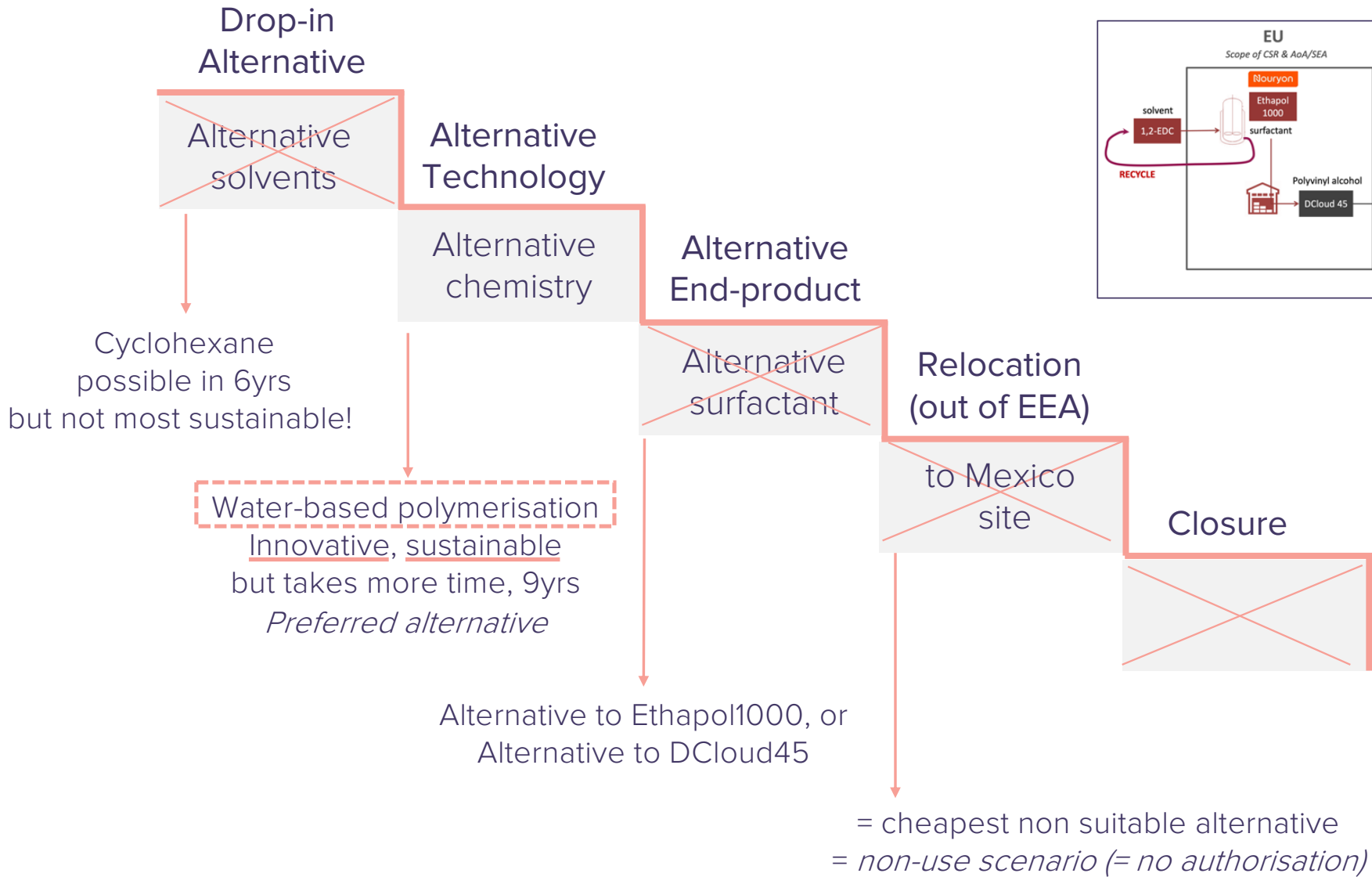
€ HH during review period
= ca. 262€



0,0000168

total fatal cancers cases per year





Koen Vanduffel, Nouryon

*“If we would have received limited time,
then we would have been forced to
bet on the quickest horse.”*

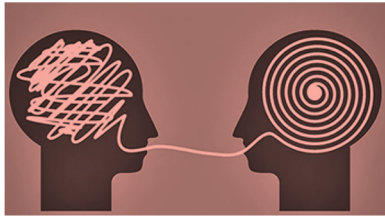
= cyclohexane, i.e. the least sustainable alternative.

Because 9 years was granted, OK to innovate for a sustainable alternative.

Authorisation was granted until 22 Nov 2026.

Development was quicker than expected, Implementation now planned in 2022!





Learning

When sufficient time is granted,
then targeted R&D can lead to
an INNOVATIVE & SUSTAINABLE alternative

If the authorised time would have been limited to 6yrs,
then the applicant would have focussed its R&D on the quickest potential alternative,
which is the least sustainable one.

Granting the applicant more time, allowed them to develop alternatives in parallel.

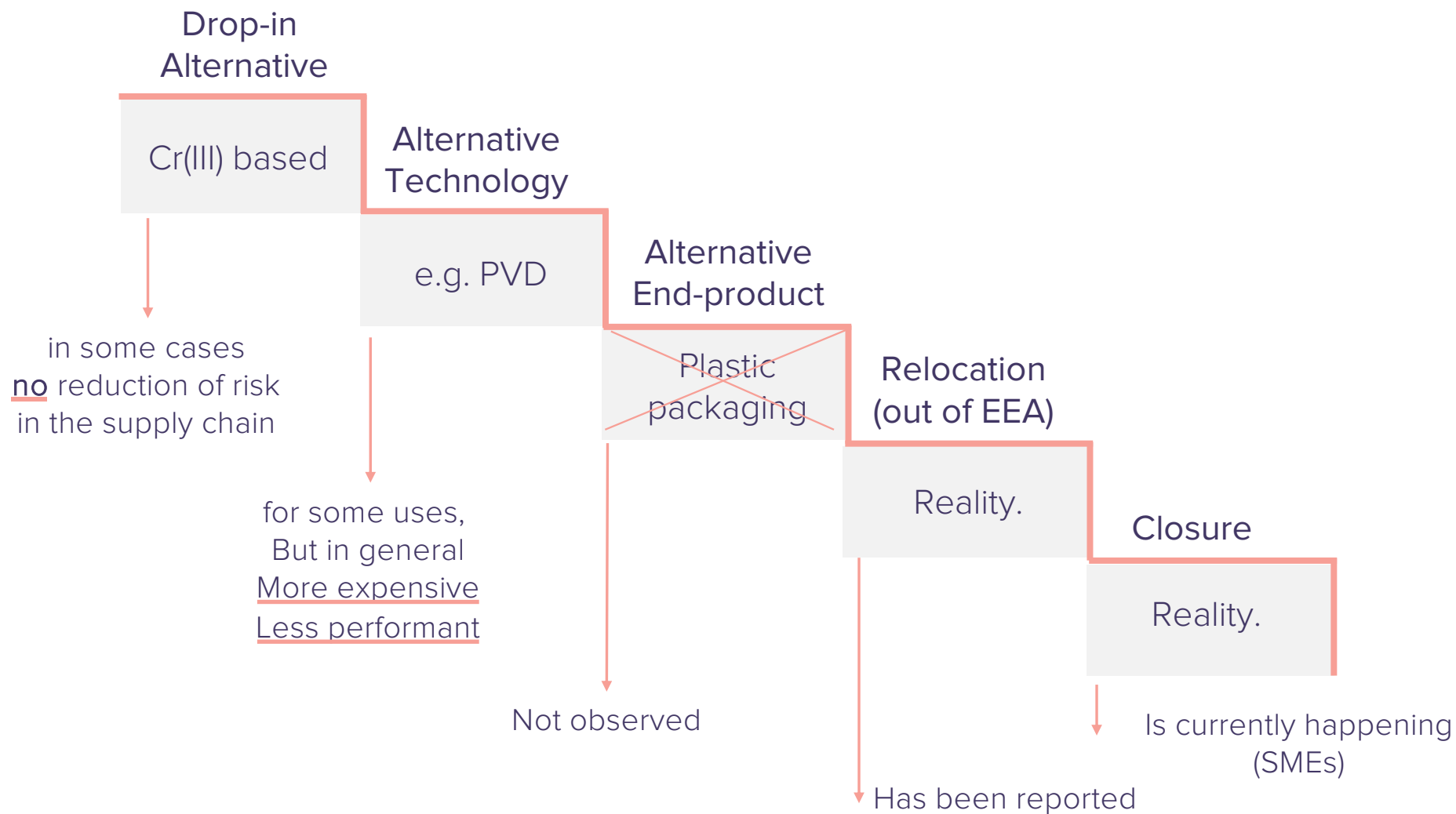


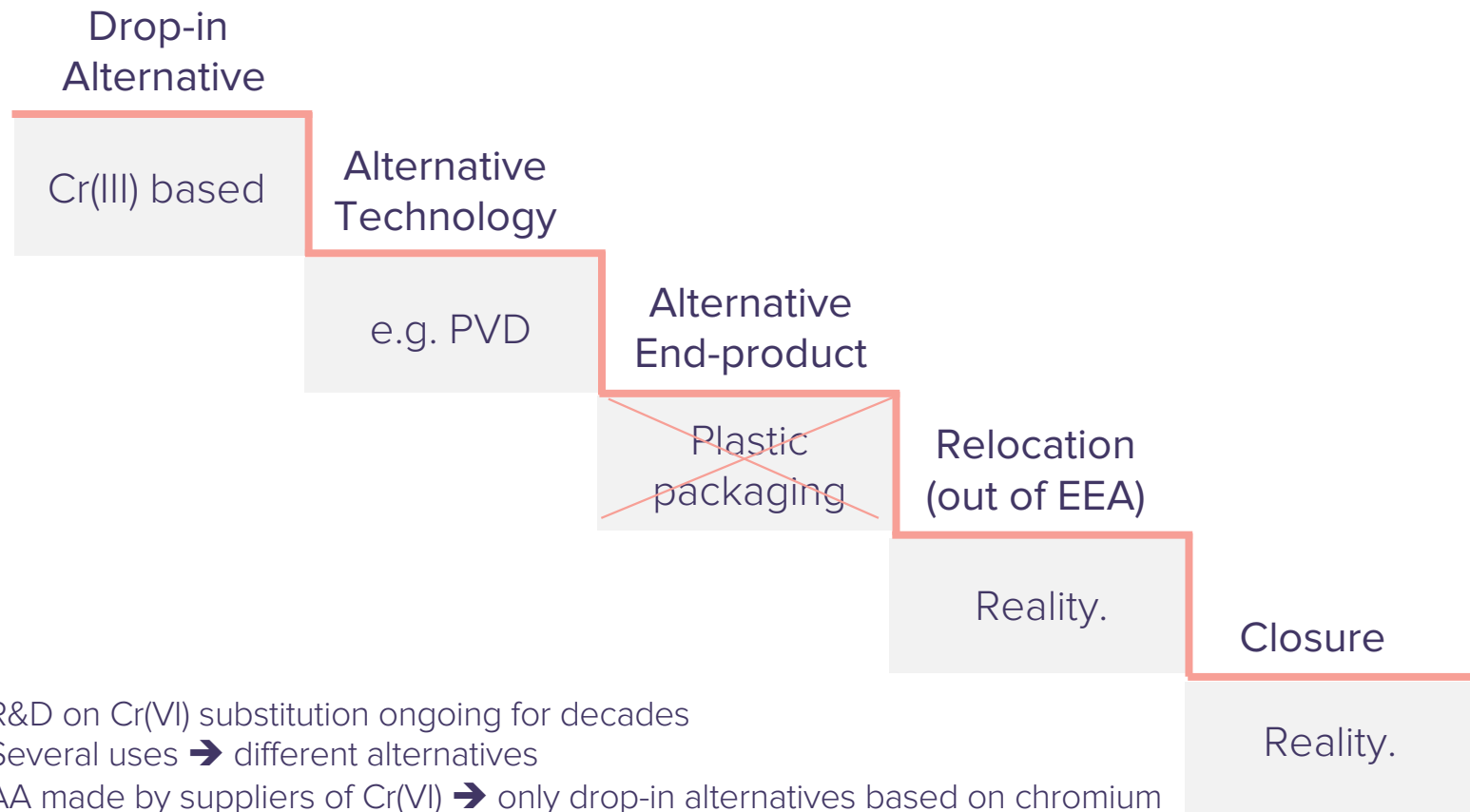
Hexavalent Chromium



- Very large number of DUs
- Various uses for surface treatment
- Various end products
 - Automotive
 - Architecture
 - Can making
 - Rifle barrels
- Concern is workers exposure





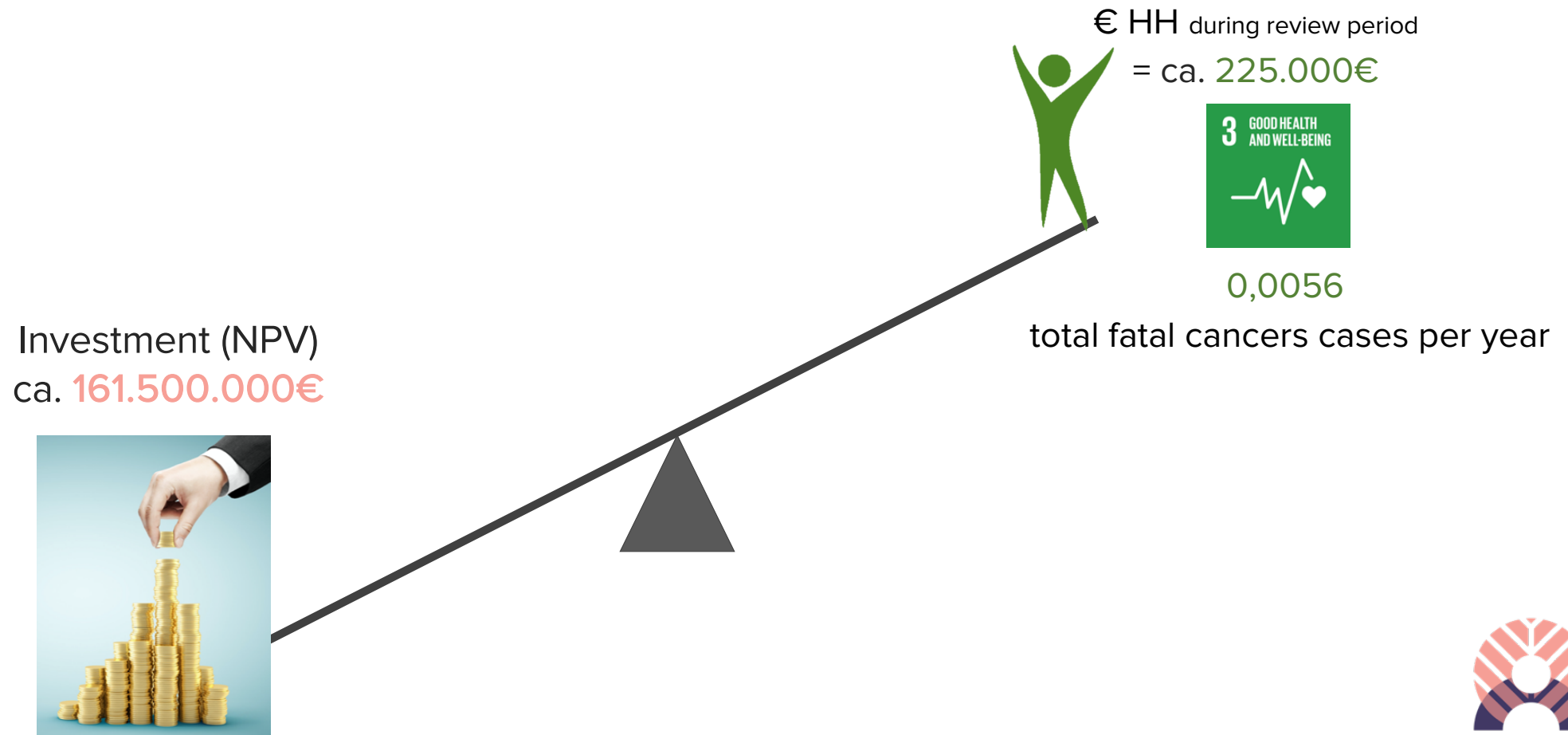


- R&D on Cr(VI) substitution ongoing for decades
- Several uses → different alternatives
- AA made by suppliers of Cr(VI) → only drop-in alternatives based on chromium
- Cr(III) still requires Cr(VI) in the supply chain (either in the production of Cr(III) compounds like Cr(III)sulfate, starting from sodium dichromate, or Cr(VI) release during mining)
- Innovative and sustainable alternative = chromium free
- Companies spent millions and substituted – with good intentions! - to Cr(III) as result of time pressure
- Substitution partially achieved, partially regrettable
- And what about the other substances in the process? Ni, borates, PFAS,
- Was it worth it?



Was it worth it?

Real life example: sum of 3 Cr(VI) authorisations



Is this
190.000.000 € from the applicants,
money well spent for SOCIETY?



What if...ALTERNATIVE-ly?



... we make the desert green again?

Project by Lignaverda <https://lignaverda.org/en/>





2010



2012



2017

Project by Lignaverda <https://lignaverda.org/en/>

190.000.000€ Investment

Hectare trees	317.300	
Ton CO ₂ /yr	1.073.500	= 107.350 Belgians (CO ₂ emission)
Cash crops/yr	5.288.333€	Gum, balanites oil
Grass/yr	3.807.600€	
Direct employment	380.000	= 1.331 villages
Indirect employment	380.000	



190.000.000€ Investment

Investment (NPV)
ca. 161.500.000€



471.000.000€ *



*NPV (4%) 20yrs
incl. cash crop, grass, CO₂ capture
HH cost of Cr(VI) use deducted



INDIRECT IMPACTS

PLANET



PEOPLE



PROSPERITY



PARTNERSHIPS

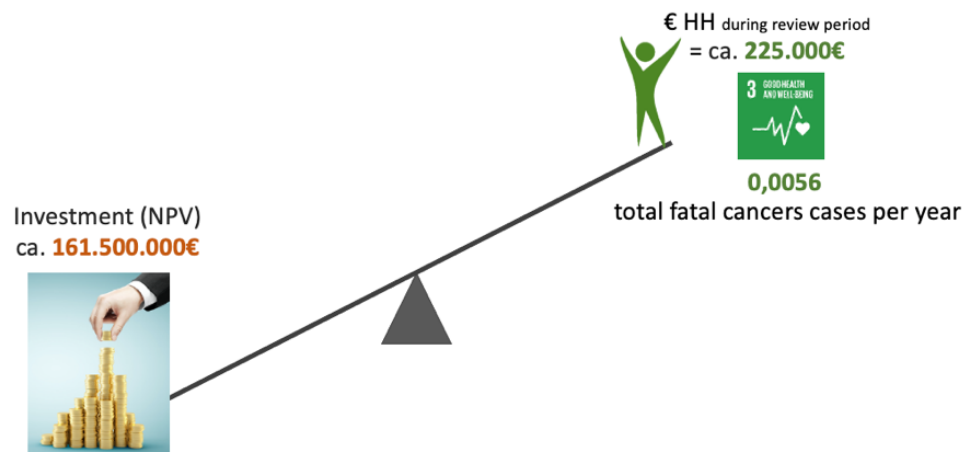


PEACE (STOP MIGRATION)

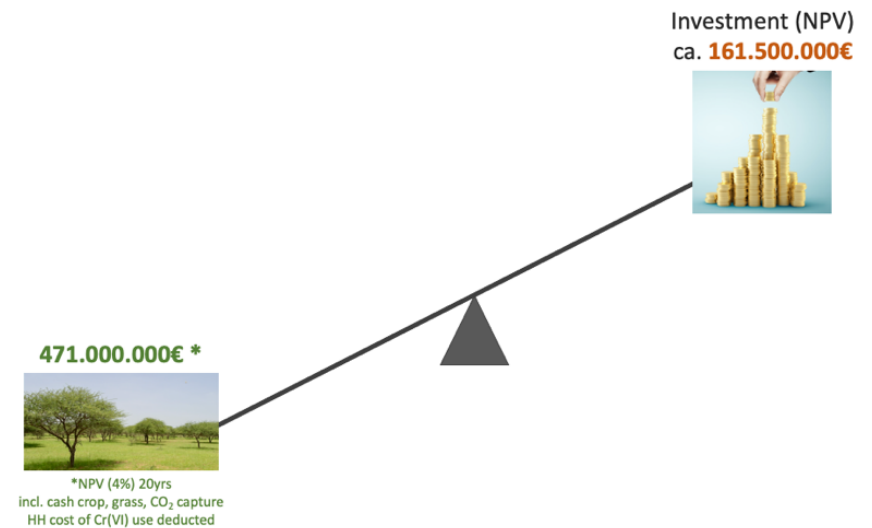


Alternatives Assessment of Investment

Alternative A: Substitute SVHC



Alternative B: Make dessert green





Learning

Regrettable substitutions in view of
overall risk (Cr(III) still leads to Cr(VI) exposure higher up in supply chain),
societal considerations & wasting resources

PRIORITY SETTING for substitution is key

First those with **maximum positive impact for society**

Substances not leading to exposure of general population should not be the first priority.

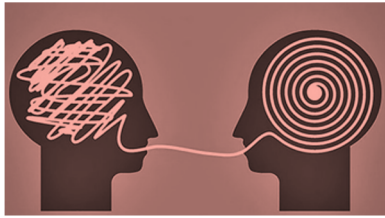
These can be tackled when the bigger problems are solved.

In the mean time the risk can be mitigated (e.g. Binding OEL)



What can we CONCLUDE
for companies
outside EU?





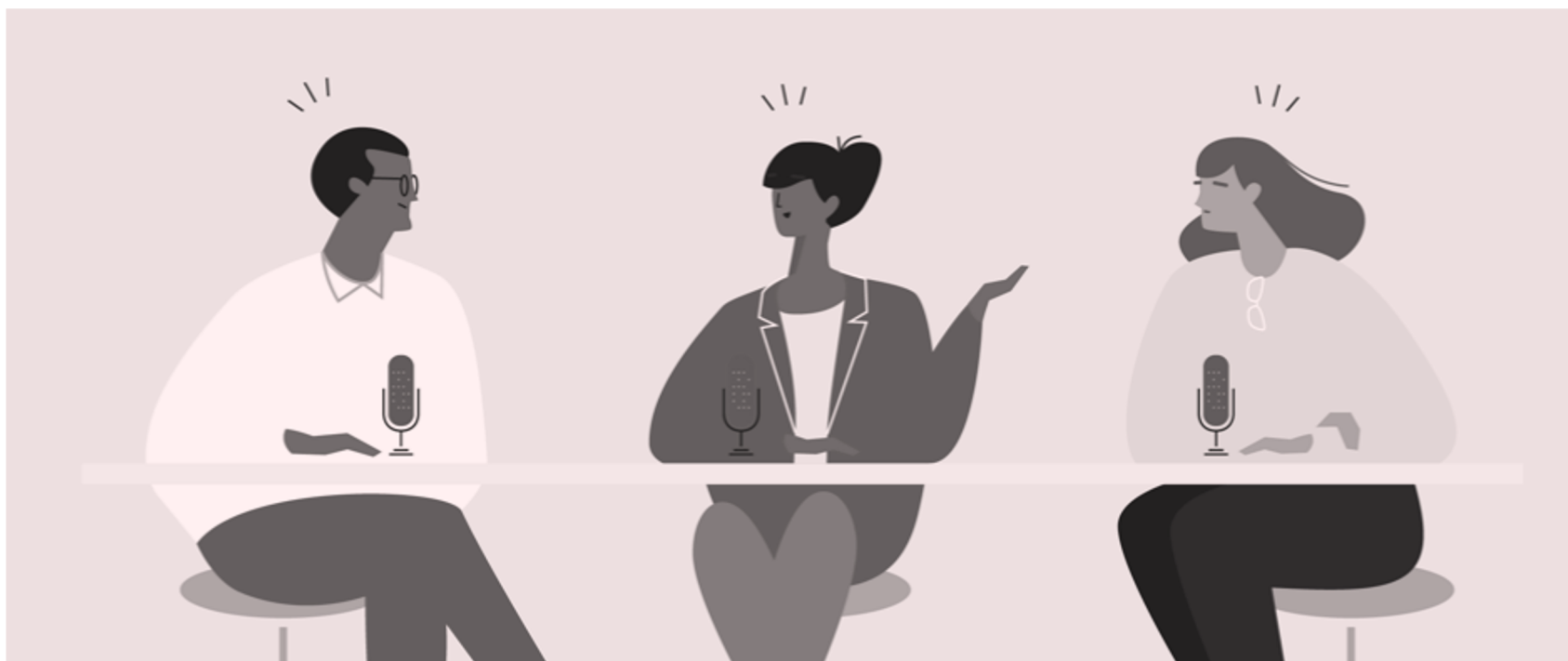
Learning

- Regulation drives Innovation
- Proactive AA are more effective
- AA is multidimensional (tox, climate, circularity)
- Innovation requires TIME
- Innovation requires insight knowledge from the downstream user
- Innovation shall consider the entire life cycle, to avoid a shift of the risk
- A priority setting for substitution is key.

Optimal use of resources to **maximize positive impact for society**



QUESTIONS AND ANSWERS



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