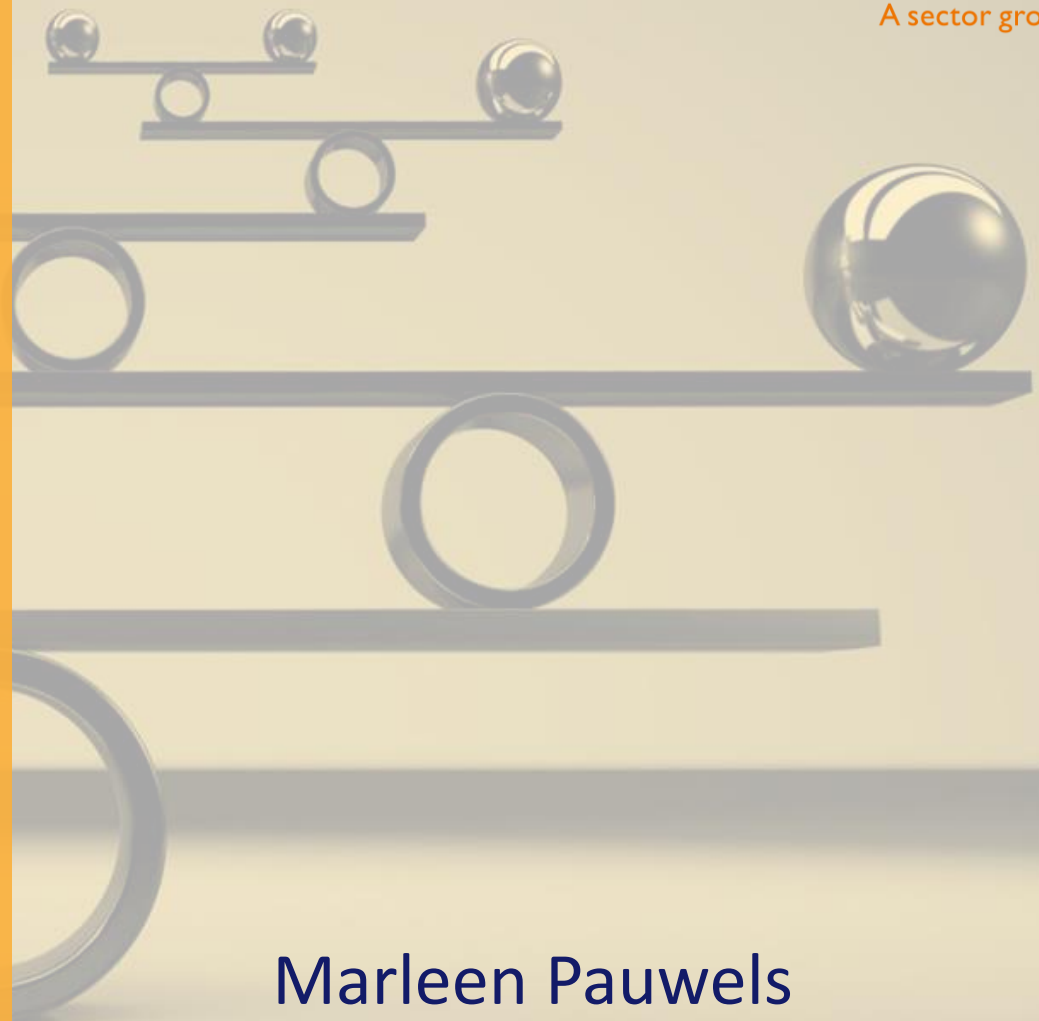
The FPP4EU proposed decision tree (food for thought)



Marleen Pauwels

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FPP4EU covers a complex sector

To group or not to group

The decision tree

Warm call for collaboration

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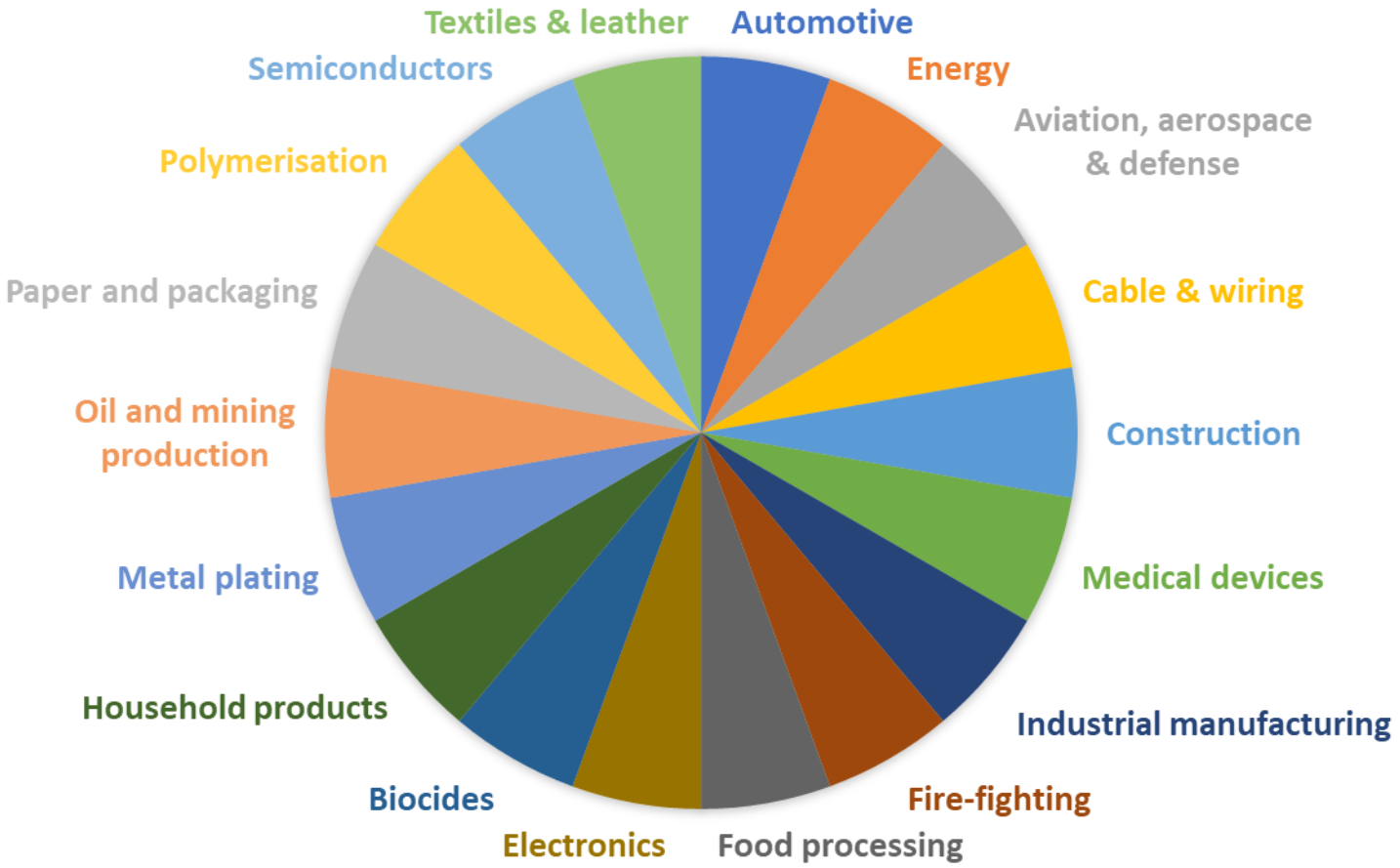
We are dealing with hundreds of substances with diverging properties, used in many applications across an extended value chain.



FPP4EU covers a complex sector

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Collaboration Platform

± 90 members

Workshops with stakeholders

OUR DOWNSTREAM USERS COVER THE MAJORITY OF INDUSTRIAL ECOSYSTEMS!!

https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-industrial-strategy_en

FPP4EU covers a complex sector

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We are dealing with hundreds of substances with diverging properties, used in many applications across an extended value chain.

We wish to be a valued partner in the wide PFAS REACH restriction

- From the manufacturers' side:
  Which (type of) data are lacking? Are there questions for us?
- From the users' side:
  How can we assist in completing the value chain mapping?

We started our own reflection

- How could PFAS be grouped in the context of a REACH restriction?
- What elements could be useful in the process of granting derogations?

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Can grouping work for the wide PFAS REACH restriction?

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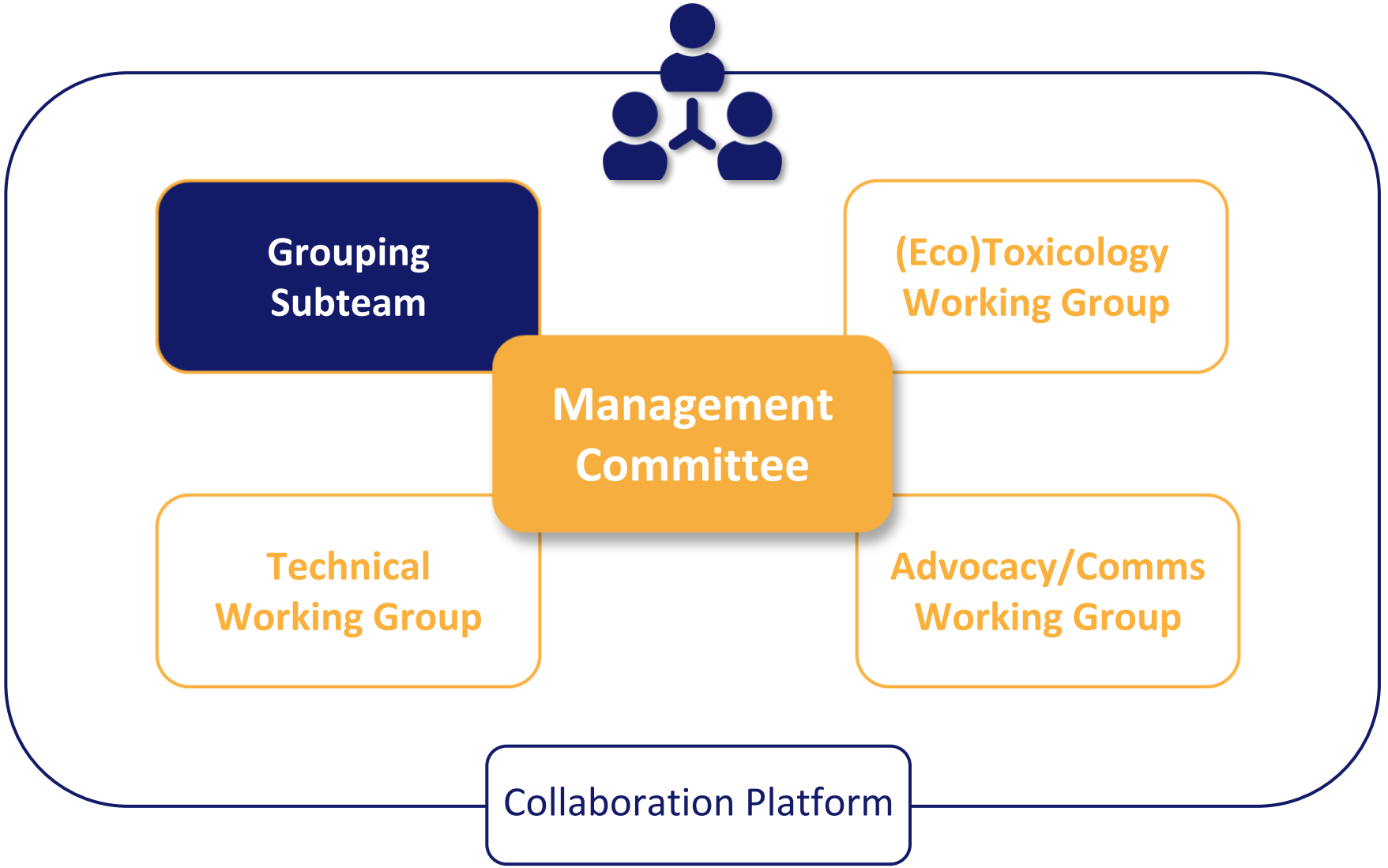

Can grouping work for the wide PFAS REACH restriction?

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Per- and Polyfluoroalkyl Substances (PFAS)

Perfluoroalkyl acids and perfluoroalkylether acids (PFAA), e.g.

perfluoroalkyl carboxylic acids (PFCA), C_nF_{2n+1}-COOH, e.g. PFOA

perfluoroalkane sulfonic acids (PFSA), C_nF_{2n+1}-SO_3H, e.g. PFOS

perfluoroalkyl phosphonic acids (PFPA), C_nF_{2n+1}-PO_3H_2

perfluoroalkyl phosphinic acids (PFPiA), $(C_nF_{2n+1})(C_mF_{2m+1})$-$PO_2H$

perfluoroalkylether carboxylic acids (PFECA), e.g. $C_2F_5OC_2F_4OCF_2COOH$

perfluoroalkylether sulfonic acids (PFESA), e.g. $C_6F_{13}OCF_2CF_2SO_3H$

Precursors to PFAA, e.g.

perfluoroalkane sulfonyl fluoridess (PASF)
perfluoroalkanoyl fluorides (PACF) and their derivatives, $C_nF_{2n+1}SO_2$-R / $C_nF_{2n+1}CO_2$-R

n:2 fluorotelomer-based substances
$C_nF_{2n+1}CH_2CH_2$-R

per- and polyfluoroalkylether-based substances
e.g. $C_nF_{2n+1}OC_mF_{2m+1}$ -R

→ **side-chain fluorinated polymers** e.g. (meth)acrylate, urethane, or oxetane polymers with non-fluorinated backbones and fluorinated side-chains

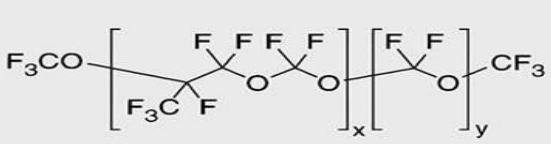
→ **non-polymers** R = NH, $NHCH_2CH_2OH$, etc.

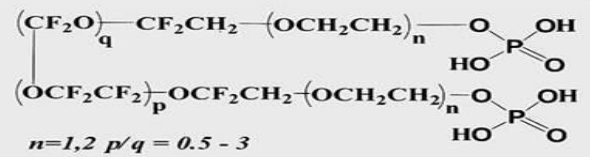
some hydrofluorocarbons (HFCs, e.g. C_nF_{2n+1}-C_mH_{2m+1}), **hydrofluoroethers (HFEs**, e.g. $C_nF_{2n+1}OC_mH_{2m+1}$) and **hydrofluoroolefins (HFOs**, e.g. C_nF_{2n+1}-$CH=CH_2$);
perfluoroalkyl ($C_nF_{2n+1}C(O)C_mF_{2m+1}$) and **semi-fluorinated** ($C_nF_{2n+1}C(O)C_mH_{2m+1}$) **ketones;**
perfluoroalkyl alcohols ($C_nF_{2n+1}OH$)

Fluoropolymers, e.g.

polytetrafluoroethylene (**PTFE**), $-(CF_2CF_2)_n-$
polychlorotrifluoroethylene (**PCTFE**), $-(CF_2CFCl)_n-$
polyvinylidene fluoride (**PVDF**), $-(CF_2CH_2)_n-$
fluorinated ethylene propylene (**FEP**), $-(CF_2CF_2)_n-(CF_2C(CF_3)F)_m-$

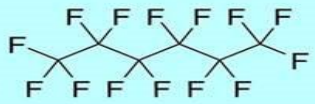
Perfluoropolyethers, e.g.





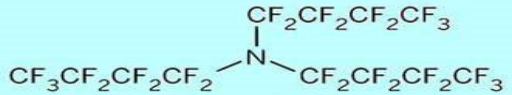
Other PFAS*, e.g.

perfluoroalkanes, e.g.



perfluoroalkylethers, e.g.

perfluoroalkylamines, e.g.



* These PFAS have been less discussed in the public domain, but they meet the definition of PFAS as recommended in Buck et al. (2011) and OECD (2018). They are primarily PFAS with limited chemical reactivity.

Kwiatkowski et al, *Environ. Sci. Technol. Lett.* 2020, 7, 8, 532–543

Can grouping work for the wide PFAS REACH restriction?

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OECD, 2021
Series on Risk Management No. 61
https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-per-and-polyfluoroalkyl-substances.pdf

Can grouping work for the wide PFAS REACH restriction?

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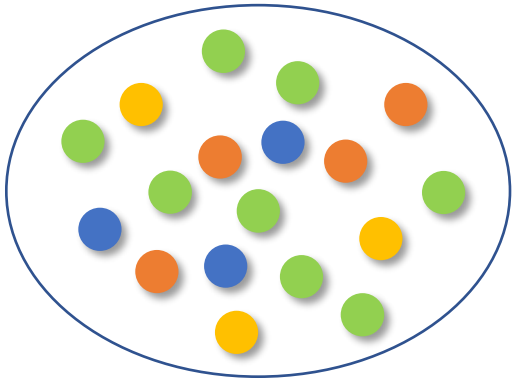
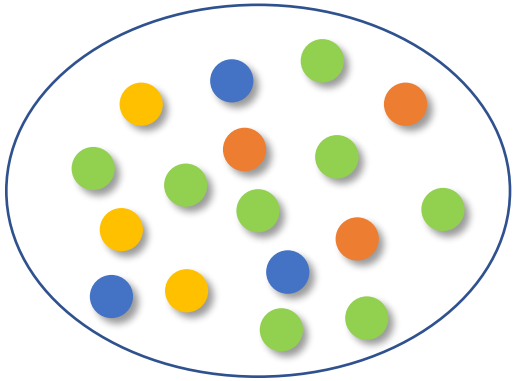
Take a glance at this hypothetical situation

Chemical class A



Chemical class B



- Non-persistent, no specific hazards identified
- Acute Tox 4, Persistent, Aquatic Chronic 2
- STOT RE 2, Mobile, Acute Tox 4
- Acute Tox. 4, Skin Corr. 1A, Aquatic Chronic 3

There are combinations of properties (not just one property) to be considered

Our conclusion :
Grouping in chemical classes does not help

Can grouping work for the wide PFAS REACH restriction?

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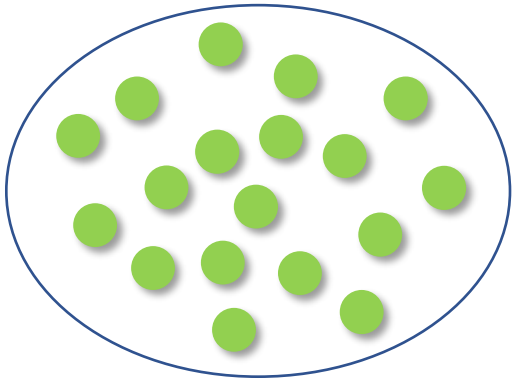
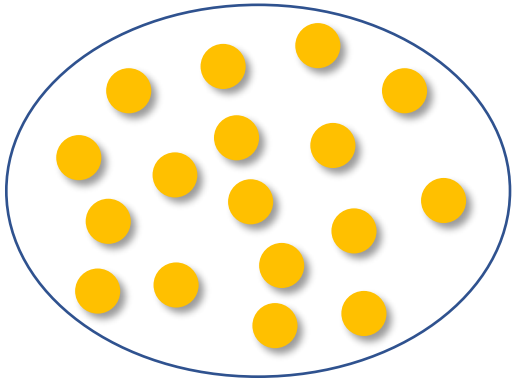
Take a glance at this hypothetical situation

Science-based class X



Science-based class Y



- Non-persistent, no specific hazards identified
- Acute Tox 4, Persistent, Aquatic Chronic 2

Our conclusion :
Science-based classes are too complex to be clearly defined

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The decision tree

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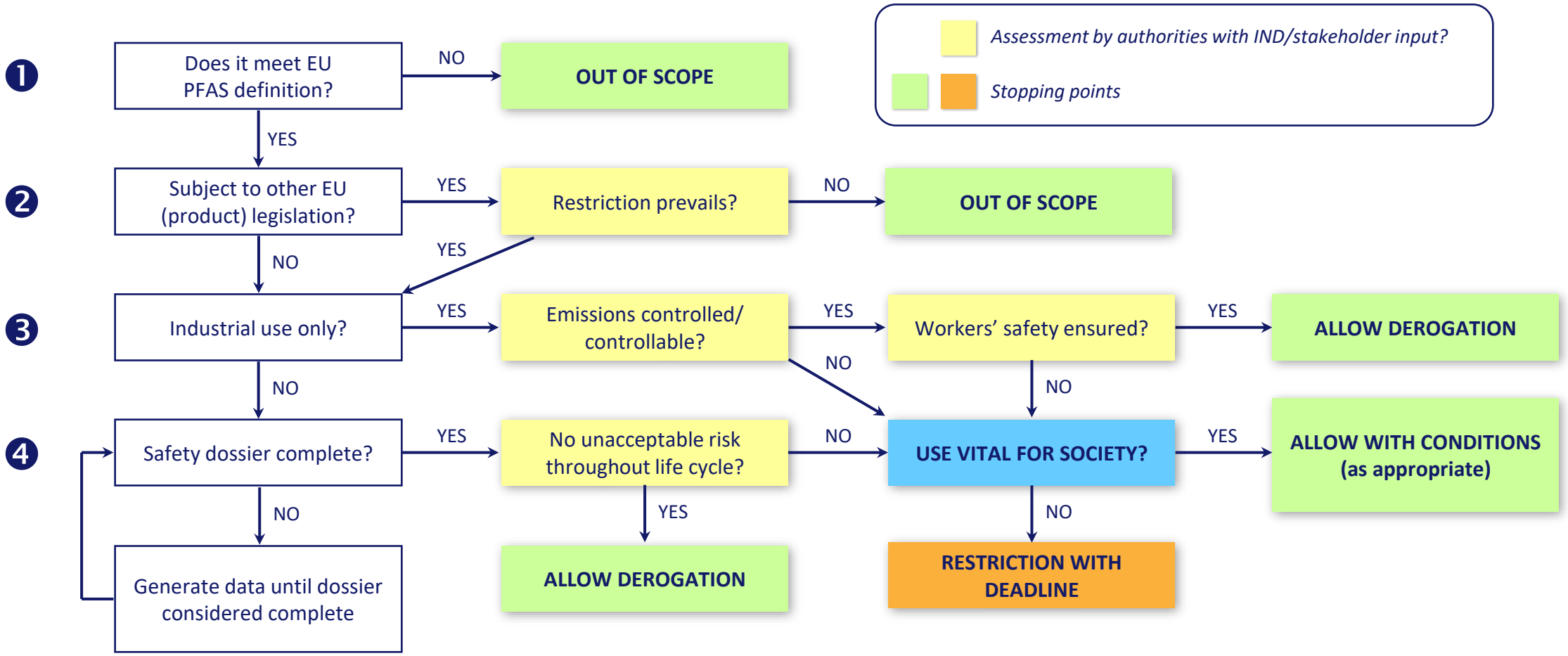
FPP4EU supports the idea of a decision tree



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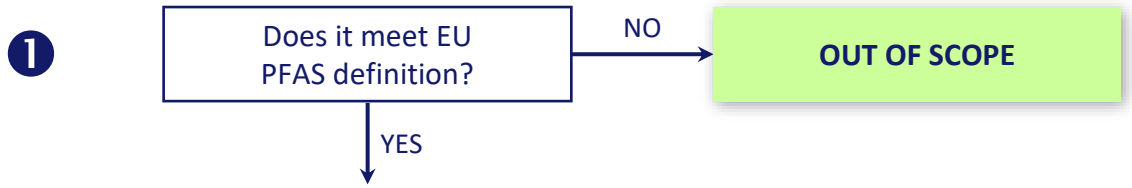

- The tree follows the definition of PFAS used in the EU REACH restriction process.
- Breakdown products will also run through this process.
- Should certain categories of PFAS, either or not combined with specific uses, be covered by their own concept/ decision trees via other associations, we refer to those instead of our proposal.

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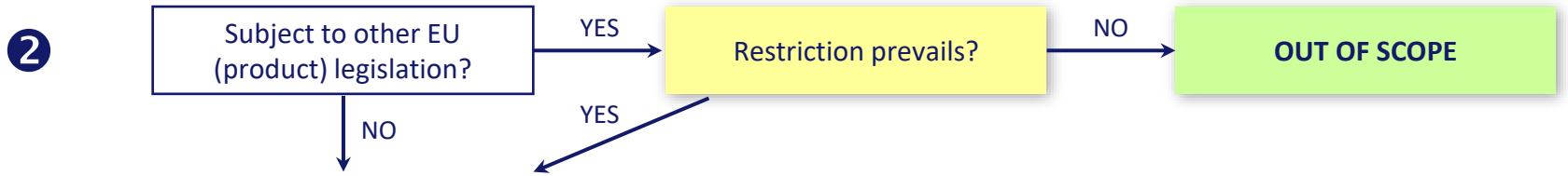
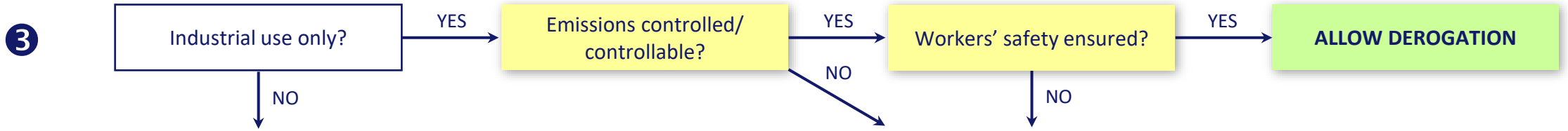


- Here we refer to the decision taken by authorities on whether restriction prevails, within the spirit of Better Regulation and ‘One Substance One Assessment’ principles.

FPP4EU supports the idea of a decision tree



In the industrial setting, process-related controls exist:

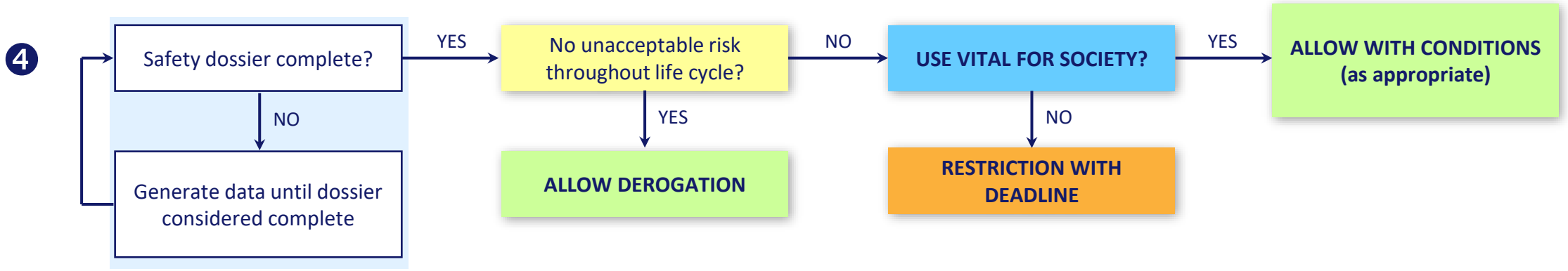
- focus on industrial emissions (current and future IED-BREF),
- focus on workers' safety (current and future OSH/ REACH).

Examples of industrial use (non-exhaustive list) may include:

- intermediates only,
- processing aids,
- PFAS used in equipment (pipes/gaskets/membranes etc.),
- etc.

Such industrial use PFAS are not intended to end up in consumers products/articles.

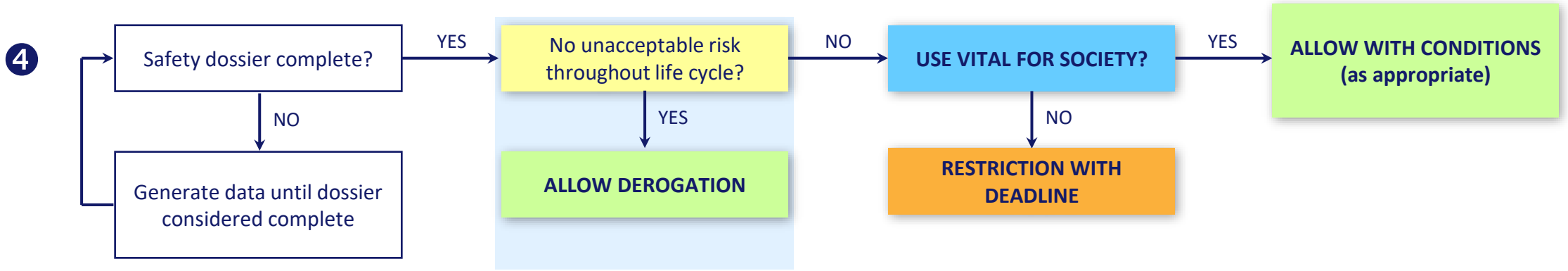
FPP4EU supports the idea of a decision tree



When is a safety dossier considered to be 'complete'?

- Company/ consortium prepares the dossier according to EU REACH requirements (including data, data waivers, read-across proposals, testing proposals etc.).
- 'Completeness' will to be confirmed/ rejected by authorities during compliance checks.

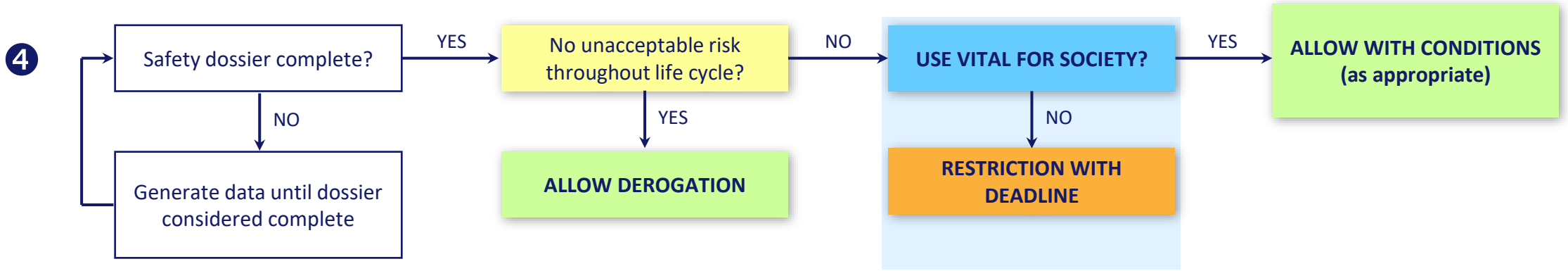
FPP4EU supports the idea of a decision tree



Risk assessment

- As per the EU REACH legal text, it must be assessed whether the substance poses any unacceptable risk to human health or the environment.
  Risk assessments are linked to function/ use/ exposure patterns and are based on important properties/ features:
  - Physico-chemical properties, incl. size/molecular weight, physical state, Kow, etc.
  - Presence in the environment (different media)
  - Official status of PBT, CMR , ED, …
  - Human data, New Approach Methodologies (NAMs) for risk assessment and read-across proposals
  - Potential emissions throughout life cycle (involving DUs)
  - Circularity and end-of-life considerations; appropriate disposal

FPP4EU supports the idea of a decision tree



Use 'vital' for society

- Socio-economic value of the substance in its use and the costs of substitution, evaluated ECHA's Committee for Socio-Economic Assessment, well-informed by the downstream user community → no assessment of 'essentiality for society'.
- Over time, the word 'vital' may need to be replaced by the word 'essential' or 'critical'.

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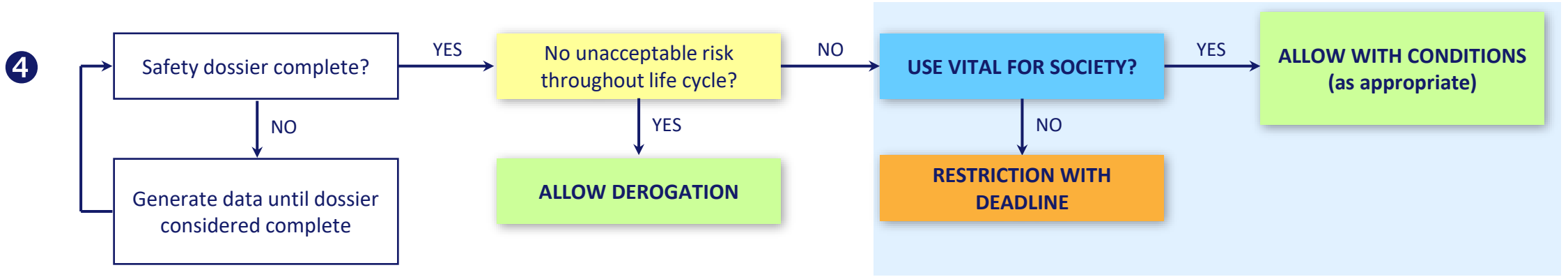

Conditions for derogations

- Companies/ downstream users can include assessments of (absence of) alternatives. Potential practical implementation timelines will also need to be considered.
- Societal debates will guide on how to deal, case by case, with (groups of) substances that may pose a health/ environmental risk but remain vital/ essential/ critical for society.

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Collaboration is our route to piecing together the puzzle

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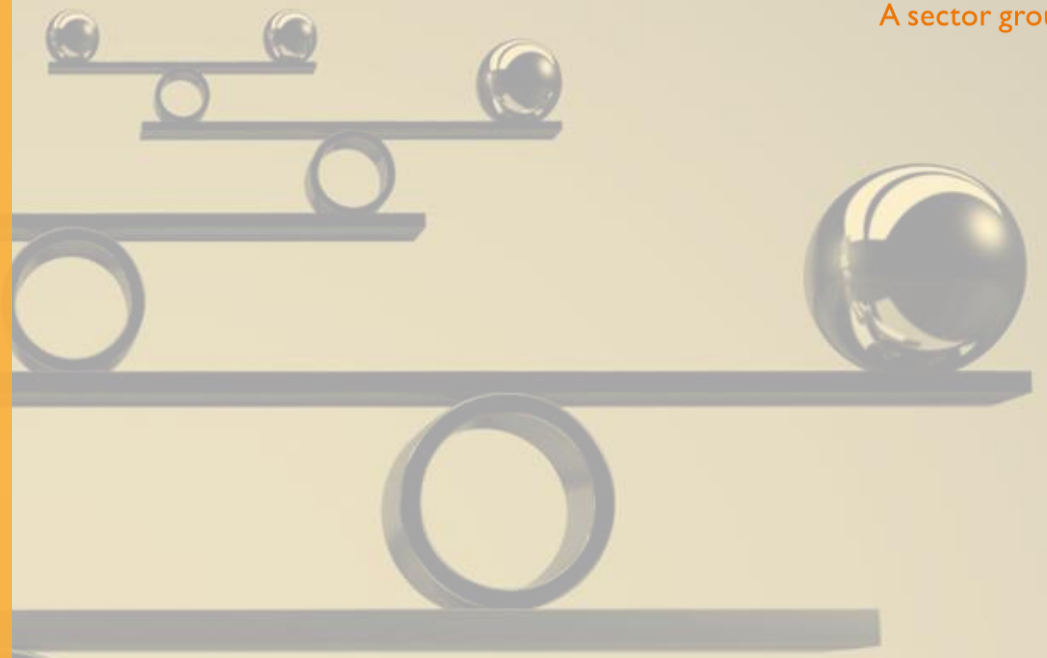
The FPP4EU proposed decision tree
(Let’s think together!)



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