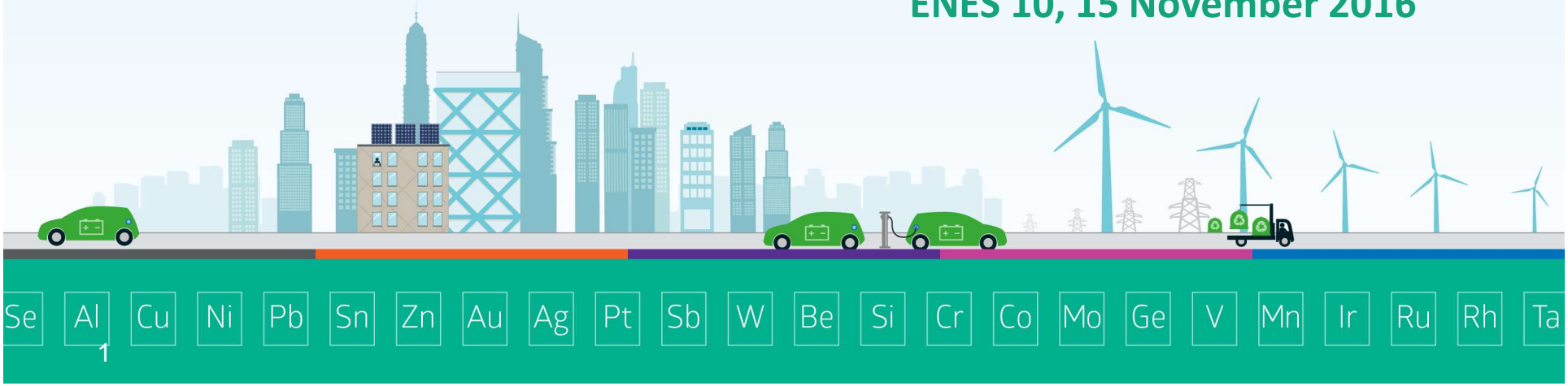
Eurometaux
European Association of Metals

How improved information included pro-actively can help registrants more convincingly demonstrate the control of risk to authorities?

ENES 10, 15 November 2016



ENES and the CSR/ES roadmap, places to…

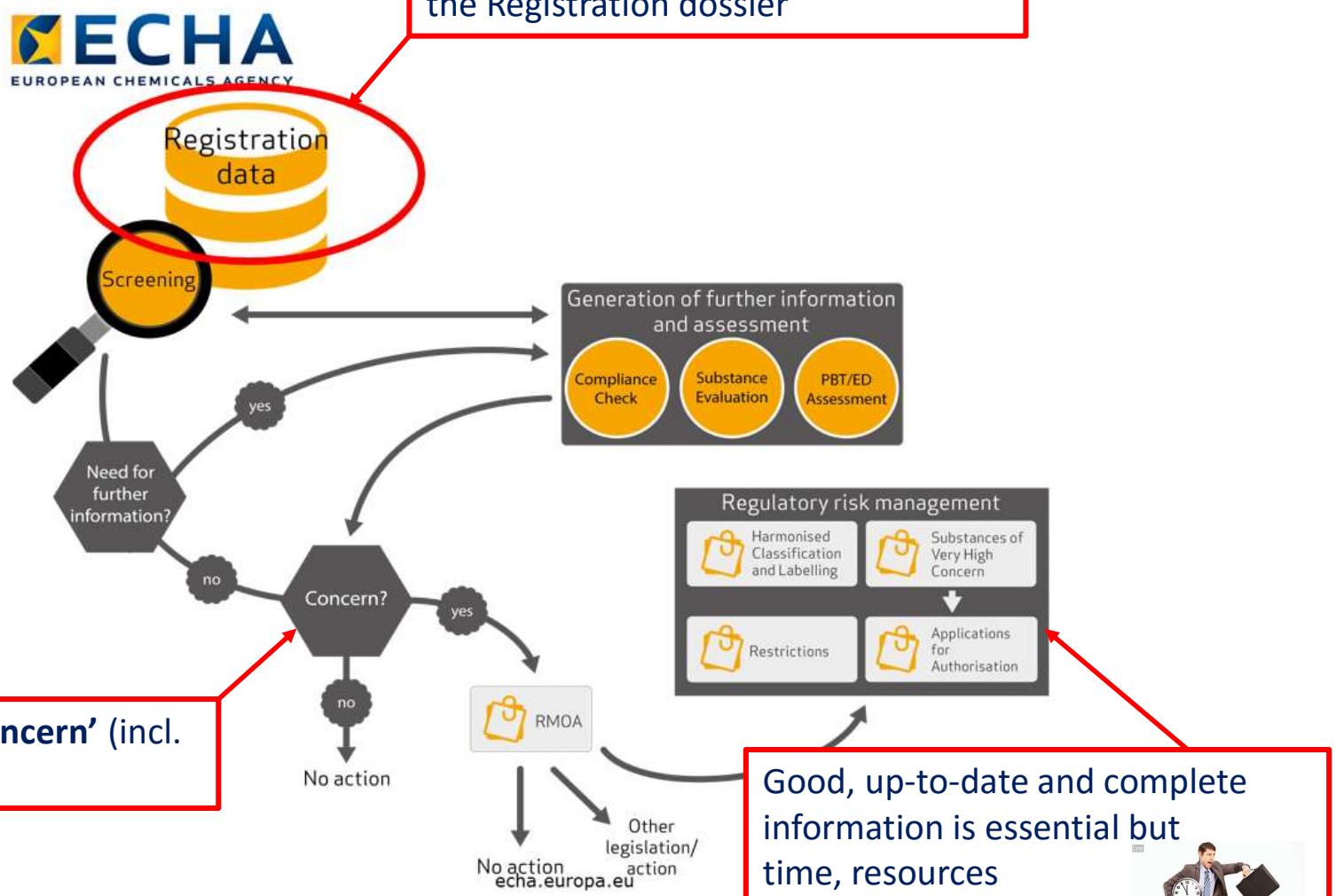
- Work further on the improvement of the quality of the information included in the registration dossiers and communicated along the supply chain

- Make best use of ‘experience’ and « best practices »

- Ensure coherence between the activities targeting the 2020 goals/Safe Use of Chemicals

Some observations…

Starting point for REACH processes is the Registration dossier



Importance of '**concern**' (incl. Exposure)

Good, up-to-date and complete information is essential but time, resources can be issues

Development of a self-reflection/risk management « preparatory tool » for industry

- To apply **ahead** of any regulatory initiative:
  - more time to explore
  - more time to develop strategies
  - more leeway for creativity and discussions

- Focused on **« concerns »** but with **'risk management'** as target

- Allowing **to optimise Registration dossier (preparation or update)**
  - Identify what counts to demonstrate/document risk management
  - Test the quality of the available data vs. a possible "RMOA"
  - Consider uncertainties on calculated values (DNEL, RCRs etc.)

- Allowing **to optimize input in regulatory processes**
  - Improves coordination of data collection and timely input
  - Allows to prepare for next steps (in case of Authorisation e.g.)

Development of a self-reflection tool for industry (2)

- A 5 steps-strategy was developed, based on case studies

Step 1 : Identify areas of concern

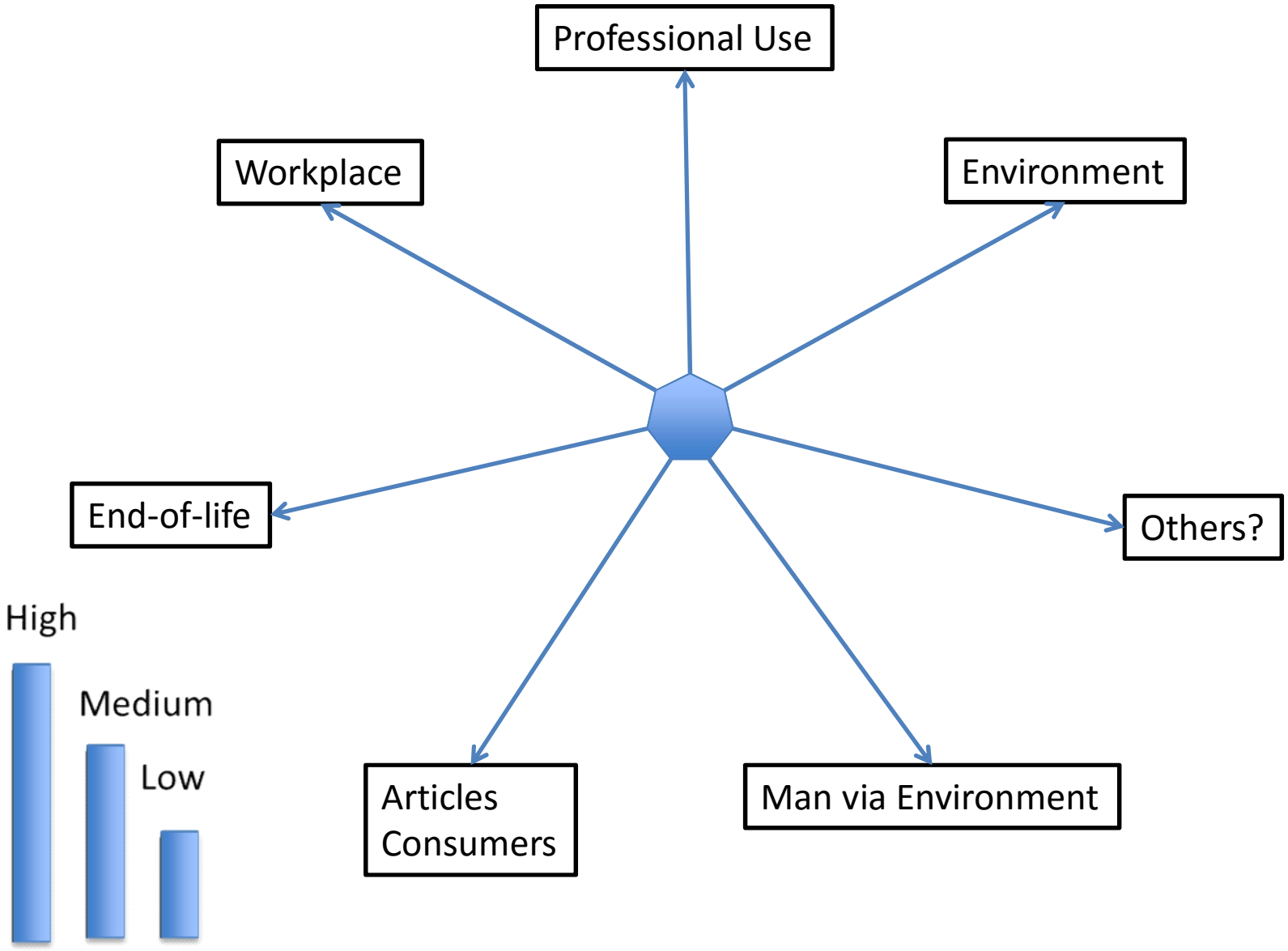
Step 2 : Identify potential Risk Management Options by use

Step 3 : Fitness tests of Risk Management Options

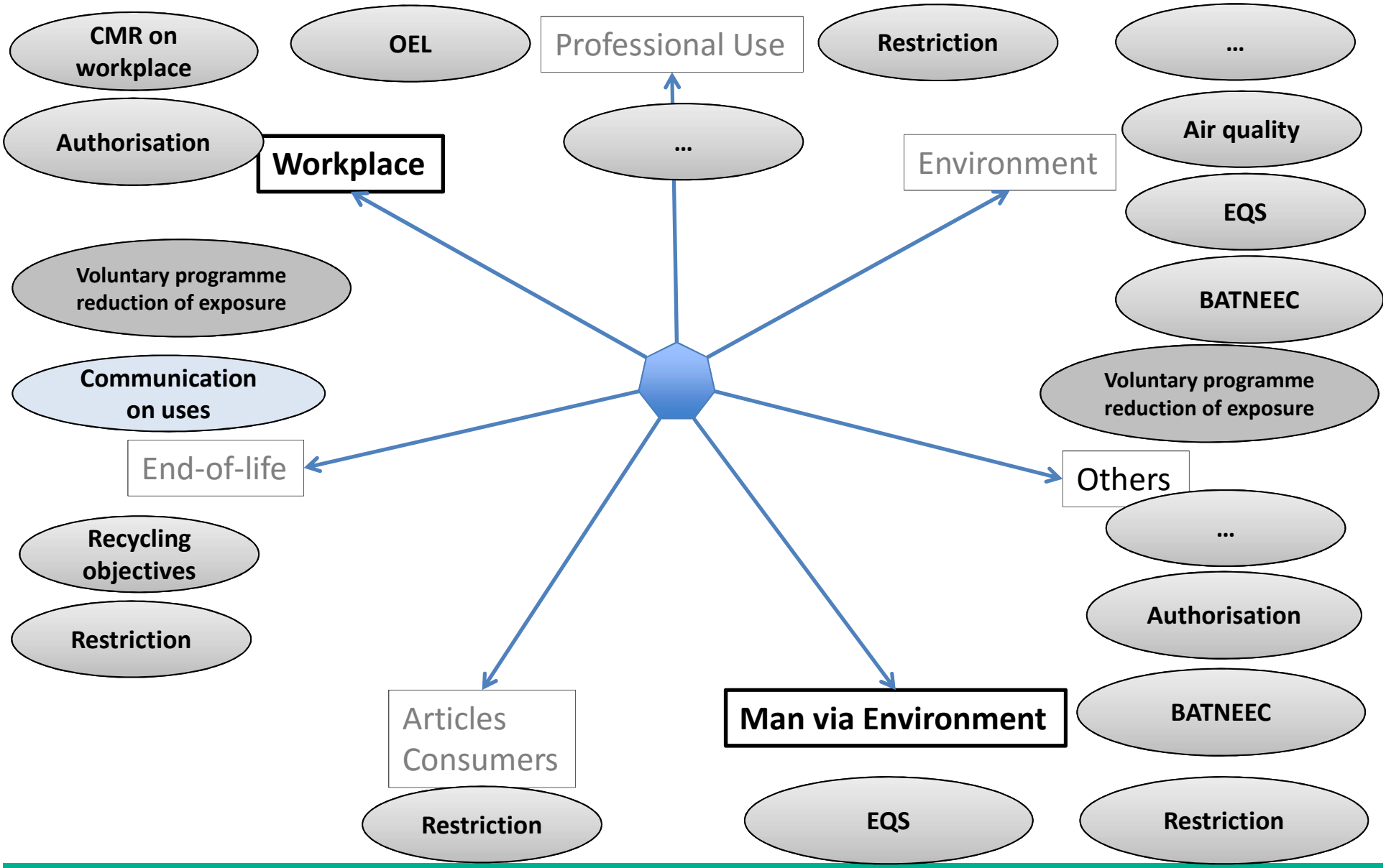
(Step 4 : Integration of RMMs/RMOas for different uses)

Step 5 : Conclusions and identification of available and missing data

Step 1 : look at your substance and identify areas of concern



Step 2: Selecting potential Risk Management Options by use



Step 3: Fitness of Risk Management Options using criteria

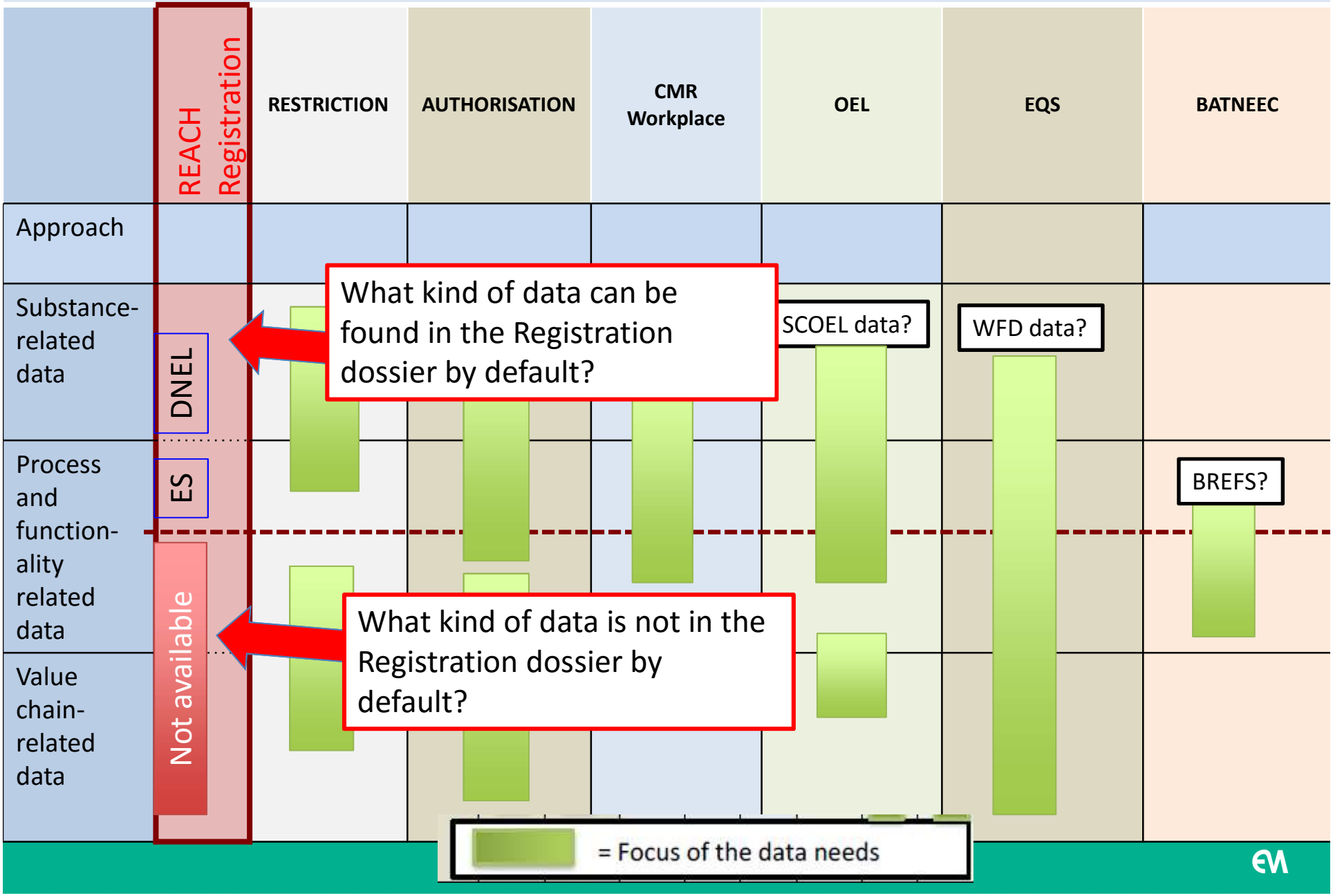
- **Effectiveness**: Is the proposed option able to reduce possible risks and will the effects be measurable?
  - *Availability of proven and affordable technology, success cases for other substances*
- **Practicality**: Can the RMO be implemented easily?
  - *Clarity on actions to be undertaken to implement the RMO, enforceability and implementability for the regulators etc.*
- **Regulatory consistency**: Is the RMO consistent with a fairly level playing field across the EU and other EU legislation /policy?
  - *Risk of significant different national implementation? Any regulatory overlaps or gaps?*
- **Broader impacts**: Are there broader economic, human health and environmental impacts worth considering affecting the value chain or society?
  - *Indirect or collateral, beneficial or detrimental effects?*

Step 4: Integrated approach for e.g. same use for different substances

Step 5: Presenting the conclusions and identification of available and missing data

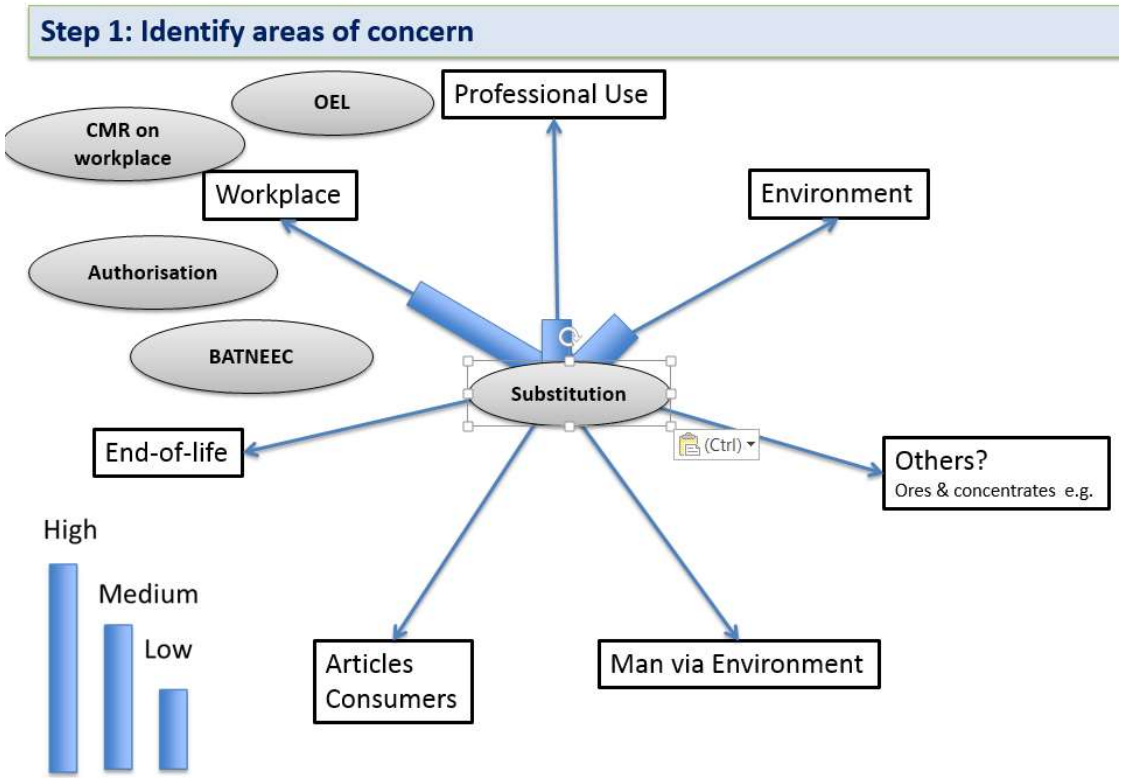
Potential RMO	CMR Workplace	OEL (binding)	Authorisation
Identified concern for substance X	**Occupational exposure (example: acid mist exposure during plating)**		
Fitness			
Effectiveness	++	++	++
Practicality	+	+	-
Regulatory consistency	-	++	++
Broader Impacts	+	+	-
Approach			
Non-Integrated	-	+	-
Integrated	++	+	+
Mixed	++	++	-
Overall ranking and conclusions	Preferred option: because most efficient and effective. Integrated/mixed approaches are OK	Second preferred option. Conclusion that here too a mixed approach is possible	Only an integrated approach might make sense

STEP 5: Mapping existing data versus further information data needs to document risk management choices to cover 'concerns' and/or anticipate RMOa requests



Use of the tool for respiratory sensitiser X

- **Aims: optimise 2018 Registration dossier & anticipate RMOas**
  - Identify what counts to demonstrate/document risk management
  - Test the quality of the available data vs. a possible “RMOA”
  - Consider uncertainties on calculated values (DNEL, RCRs etc.)



Step 5: Identification of data gaps

		REACH Registration	Accuracy	Uncertainty	Restriction	EQS	BATNEEC
Substance-related data		• Human Tox • Regulations	DNELS?	DNELS?	+ +	WFD data?	BREFS?
		• Envi Tox • Regulations	DNELS?	DNELS?	+ +	++	
Process and functionality related data	Not in Registration dossier	• Volumes (overall) • **Exposure (generic)** • Process and product regulations • **Volumes per use / process** • Functionality per use/process • **Alternatives per use/process**	Reality?	Reality?	+ + + + + + plus tox profile	+ + + + - -	+ + + + - -
Value chain-related data		• # legal entities / plants • **# Workers exposed and dependent on substance use** • **Market (volumes, trade)** • Price elasticity • Cross-value chain interrelations • Life-cycle dimensions (sustainability issues, recycling dynamics) • Costs current vs. alternatives/non-use situation • Costs current vs. new technology			+ + + + + + + If integrated approach	Regional Population Tbc Tbc + - +	+ Tbc - - - + - +

Follow-up: actions taken or planned

Exposure	• Epidemiological study • Dermal monitoring campaign
Volume/use; market info	• Survey at producers level • Survey at DUs level
Assessment of Alternatives	• AoA based on publicly available information, encourage companies to continue R&D

Benefits at an early stage:

- **Improvement of the registration dossier**
- **Better contribution in consultations and authorities RMO work**

To conclude

The tool is aimed to be used :

- As *a* ***critical mirror, self reflection*** for a sector/companies to define the potential need for risk management measures
- As *an* ***internal audit*** to allow a company to assess remaining risks & most efficient risk management measures
- Allowing to ***look from "all perspectives"*** for the need for risk management measures and relevant risk management options
- Allowing industry to ***anticipate*** "Member States -RMOas"
- As a tool to ***define the information required*** for an appropriate RMOa and probably lacking in the CSR
- As a tool to ***identify data gaps*** in or outside the registration dossiers
- As a tool for more ***risk management focused registrations*** (mainly for 2018 registrations)

Any question? Please contact :

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THANK YOU