



The European voice of the  
**adhesive** and **sealant industry**



# Diisocyanate Risk Management Issues PU Products – EU Regulatory Approach

CHEMUK2019

May 2019

# Outline



The Regulation Process



The Restriction Proposals



Training Proposals

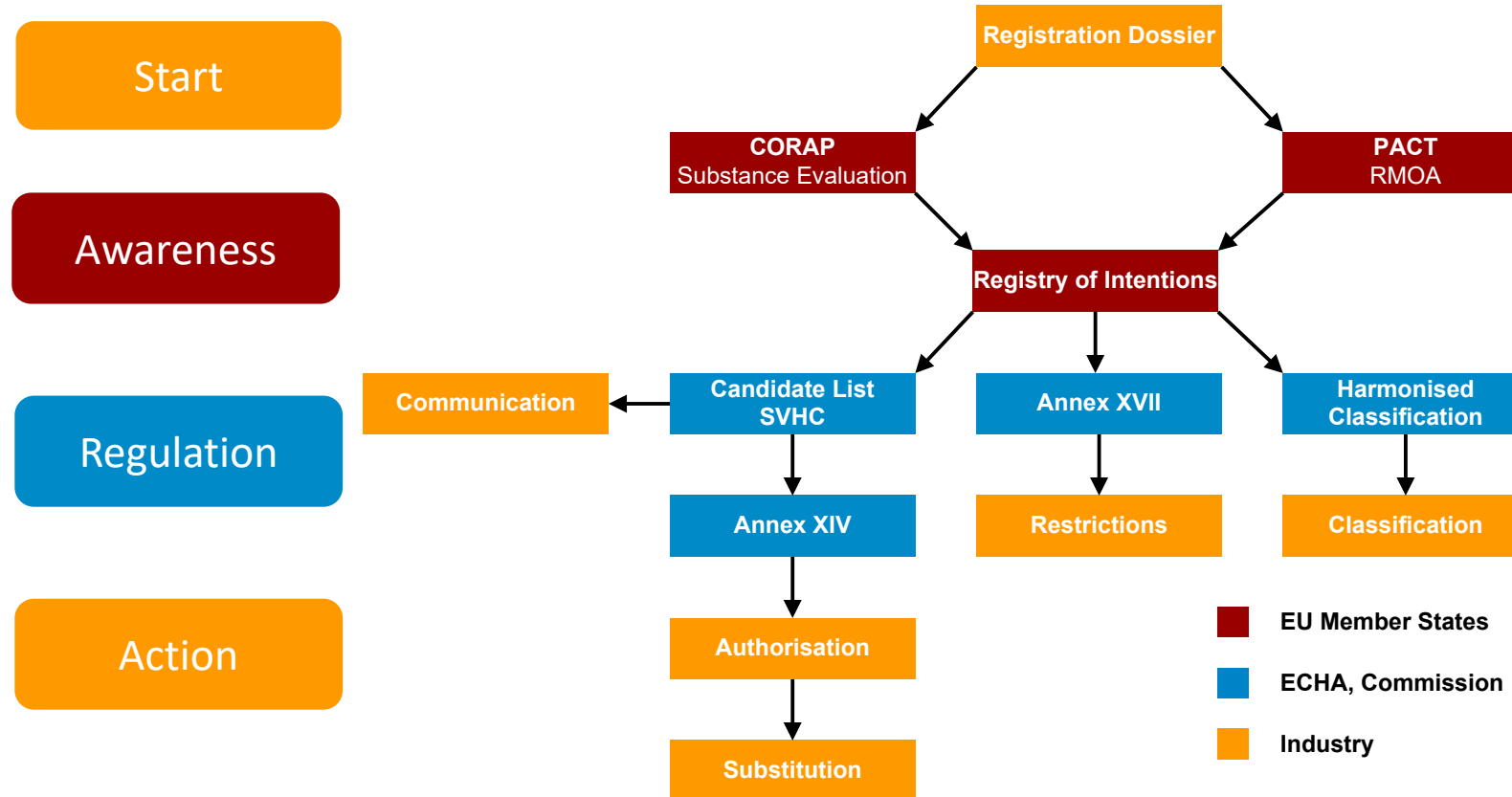


Exemptions



Downstream Communication

# Substance Regulation



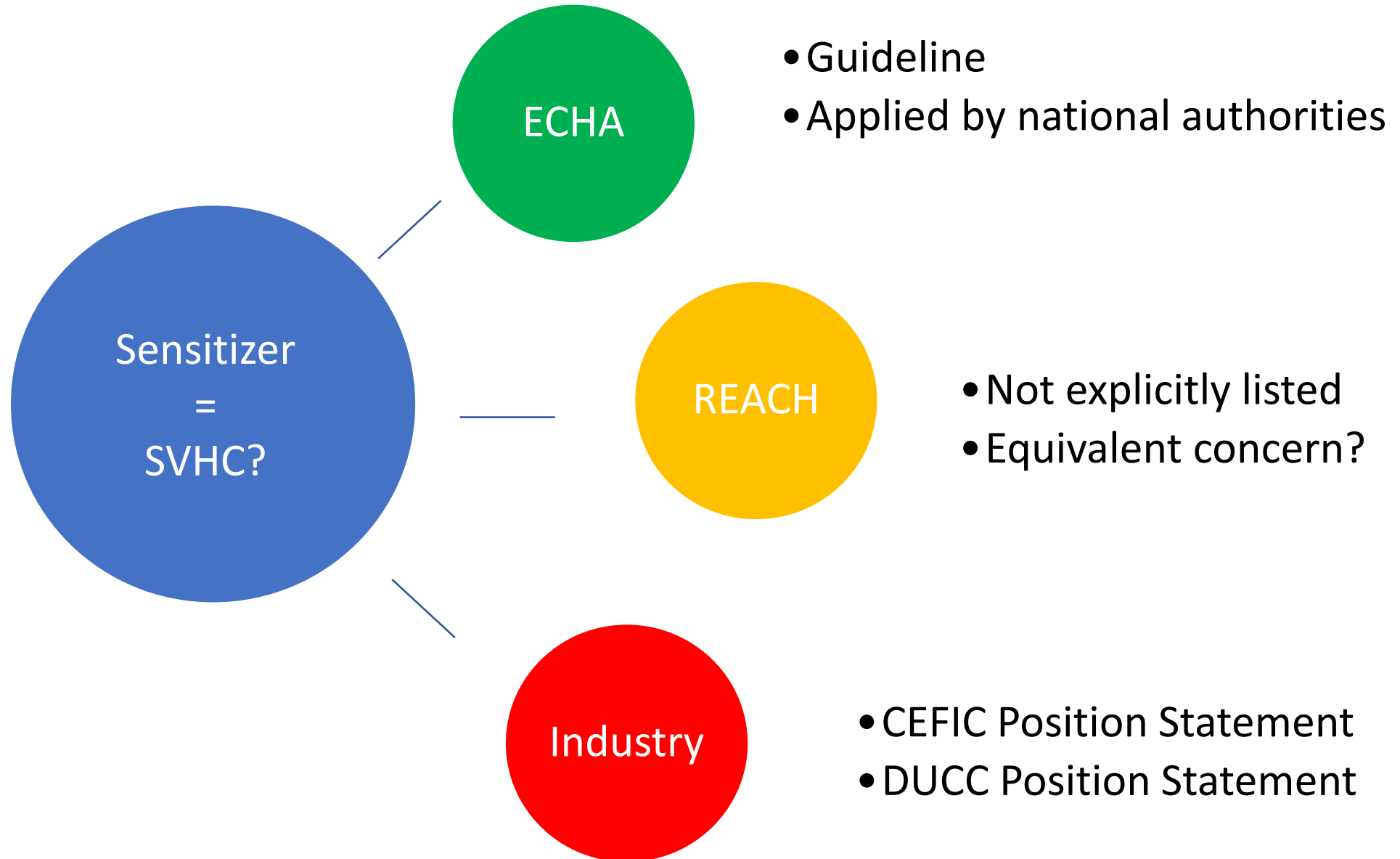
# Diisocyanate Monomer Classification



	TDI	MDI	IPDI	HDI
Acute Toxicity	Cat. 1	Cat. 4	Cat. 1	Cat. 1
STOT SE	Cat. 3	Cat. 3	Cat. 3	Cat. 3
STOT RE	—	Cat. 2	—	—
Carcinogenicity	Cat. 2	Cat. 2	—	—
Skin Irritation	Cat. 2	Cat. 2	Cat. 2	Cat. 2
Skin Sensitisation	Cat. 1	Cat. 1	Cat. 1	Cat. 1
Resp. Sensitisation	Cat. 1	Cat. 1	Cat. 1	Cat. 1
Eye Irritation	Cat. 2	Cat. 2	Cat. 2	Cat. 2
Chronic Aquatic	Cat. 3	—	Cat. 2	—



# Respiratory Sensitizer and SVHC



# Authority Activities

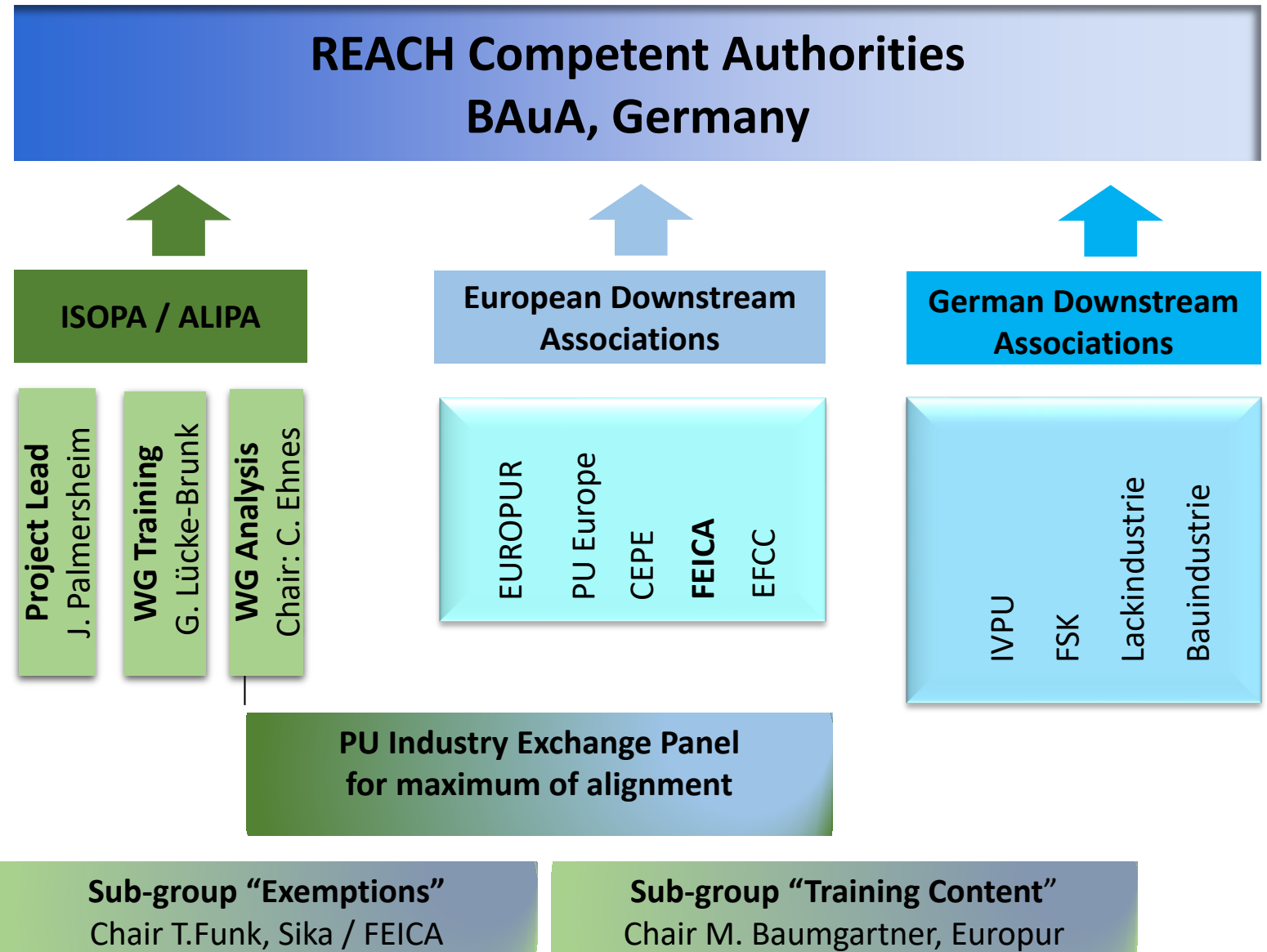
Member State	Substance	Issue Date	Subject	Targeted Action
Poland	TDI	2012	CMR, Sens., PBT	No action
Estonia	MDI	2013	CMR, Sens., PBT	Ongoing
France	Biphenyl-DI	2013	CMR, Sens., PBT	Ongoing
Denmark	TDI, MDI	2014-08	RMOA (CMR, Sens.)	On hold
Germany	Diisocyanates	2014-09	RMOA (Sensitizer)	Restriction
Sweden	IPDI	2014-09	RMOA (Sensitizer)	
Estonia	MDI	2015-04	Hazard (PBT)	
Belgium	MDI	2015-04	Hazard (PBT)	
ECHA	HDI isocyanurate	2015-04	Hazard (PBT)	
France	Biphenyl-DI	2015-04	Hazard (PBT)	



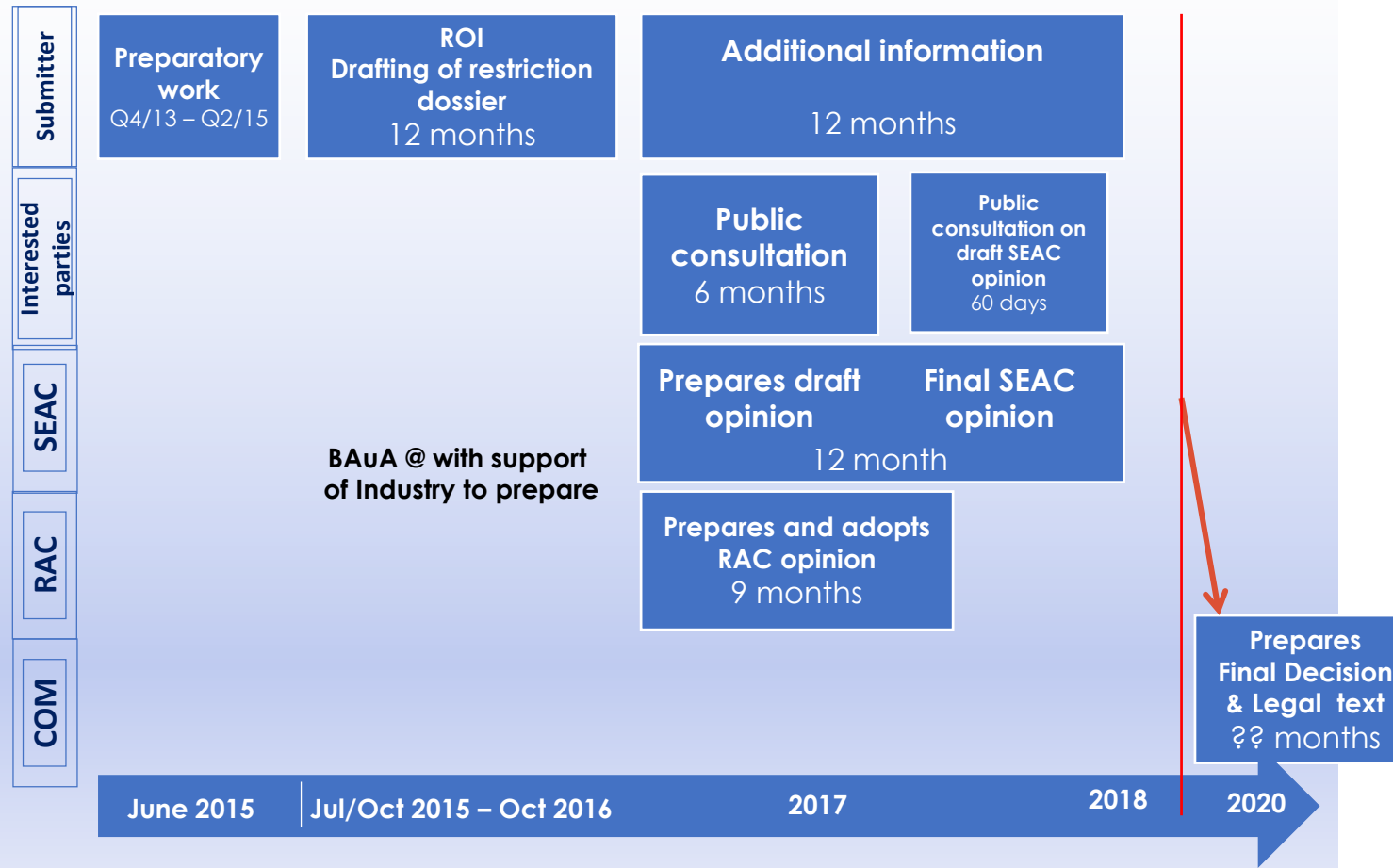
# PU Exchange Panel

## Industry Involvement

- ✓ early in the process
- ✓ registrants and DUs
- ✓ during preparation of regulation
- ✓ close cooperation between industry and authority



# REACH Process for a restriction



Transition Period



# Diisocyanate Restriction

## Diisocyanate containing products

- Shall **not be used** for industrial and professional uses
- Shall **not be placed on the market** for industrial and professional uses
- UNLESS .....

# Diisocyanate Restriction

## Conditions for further use and placing on the market

- Less than **0.1%** of diisocyanates
- or
- User has established **training and measures** for safe use
- or
- Combination of product and use is **exempted**

Authorisation as an option is not yet completely ruled out

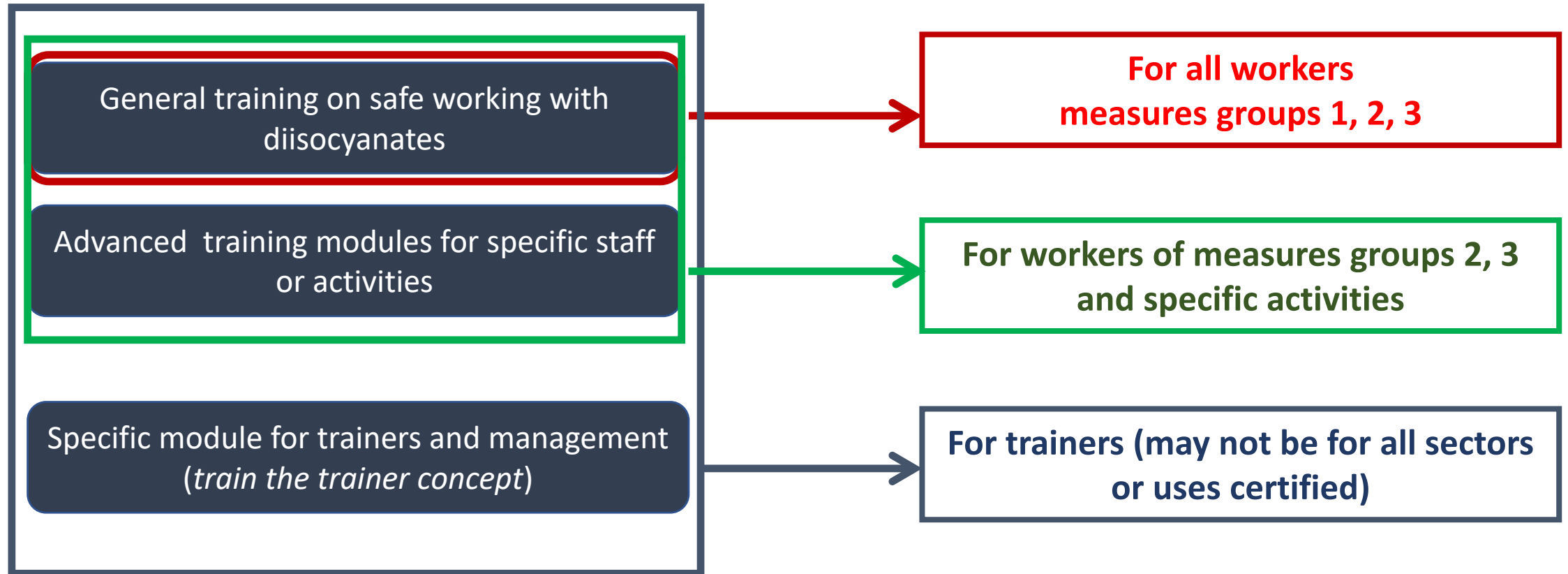
# Training and Measures

## Principle of the Training: Measures Groups

Route of Exposure	Measures group	Probability of Exposure
Dermal	1	Potential skin contact rare, small areas and immediately appropriately removed (e.g. splashes)
	2	Potential repeated short term skin contact (max. 4*15 min. per shift)
	3	Potential repeated prolonged skin contact (more than 60 min. per shift)
Inhalation	1	Low vapour formation
	2	Moderate vapour and/or aerosol formation
	3	High vapour and/or aerosol formation

# Training and Measures

Principle of the Training: Training Modules



# Training and Measures

Measures Group	Training Requirement			Measures
	Training Duration (incl. Certification)	Where	Valid [yrs]	
Management	4 h	Classroom or Workplace or Written	4	
1	4 h	Class room or Workplace or Written or E-learning	4	Technical and organizational
2	Measures Group 1 + add. 4 h	Classroom or Workplace	4	Add. technical and organizational
3	Measures Group 2 + add. 8 h	Class room and on site	4	Add. technical and organizational

# Training and Measures

Still to be defined

## Training Content

- General
- Sector specific

## Implementation

- Content responsibility
- Who will offer the training of trainers
- Time frame

# Exemptions

Product (incl. packaging, tools) in combination with the use

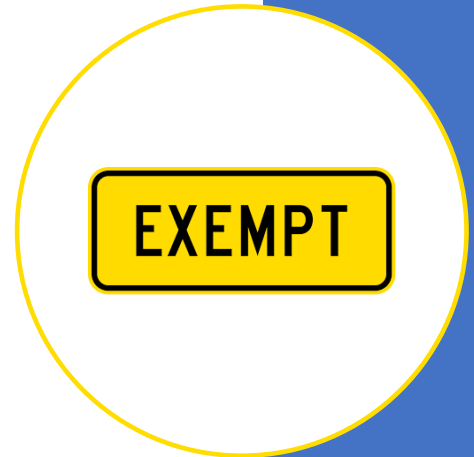
- Temperature below 45°C
- No spray application
- No technical exposure reduction

Inhalation exposure

- Air concentration of diisocyanates < 1 ppb (OEL)

Dermal exposure ?

- Qualitative estimation via Excel model
- Biomonitoring



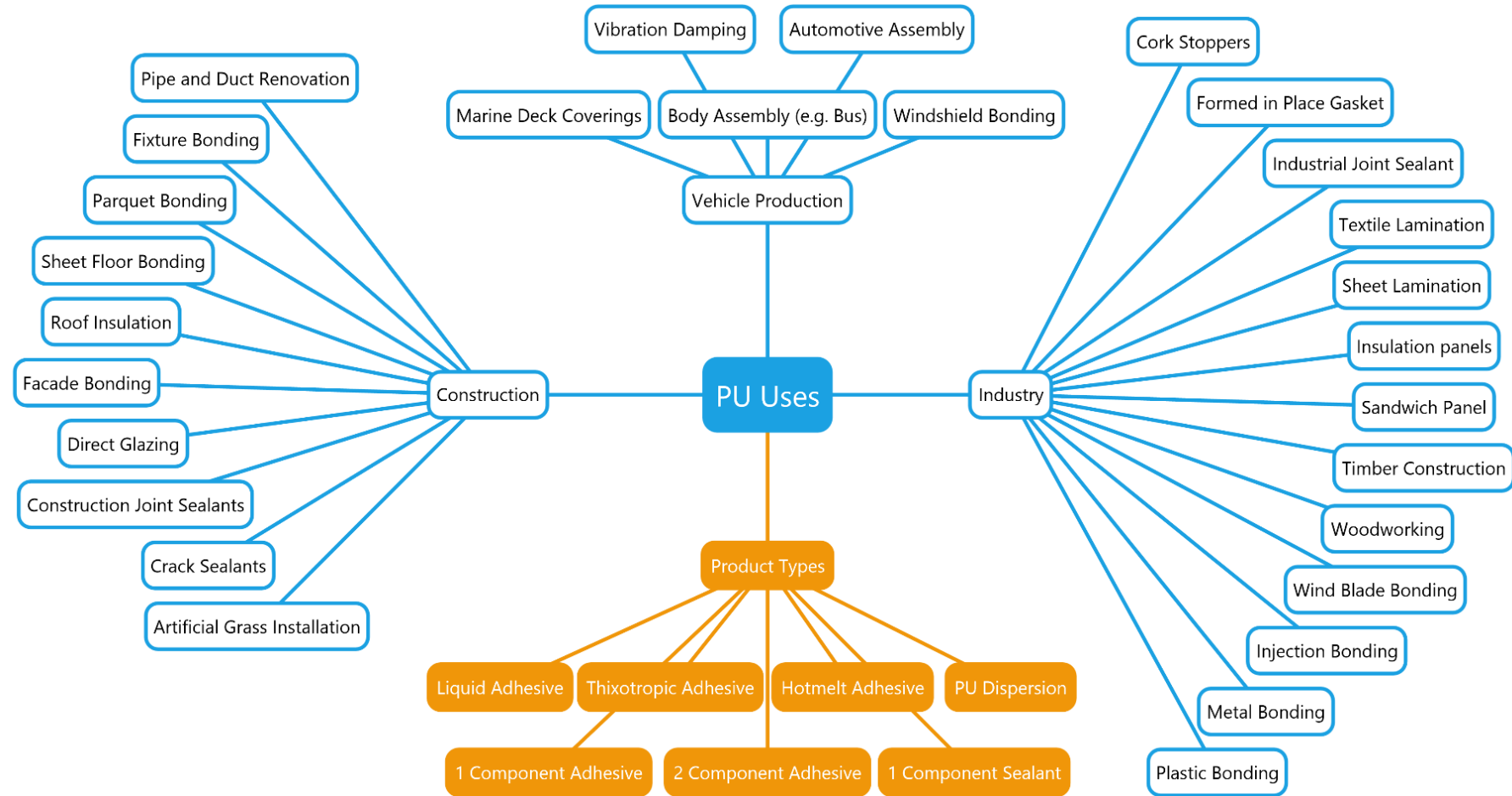
**Exemption Dossier**



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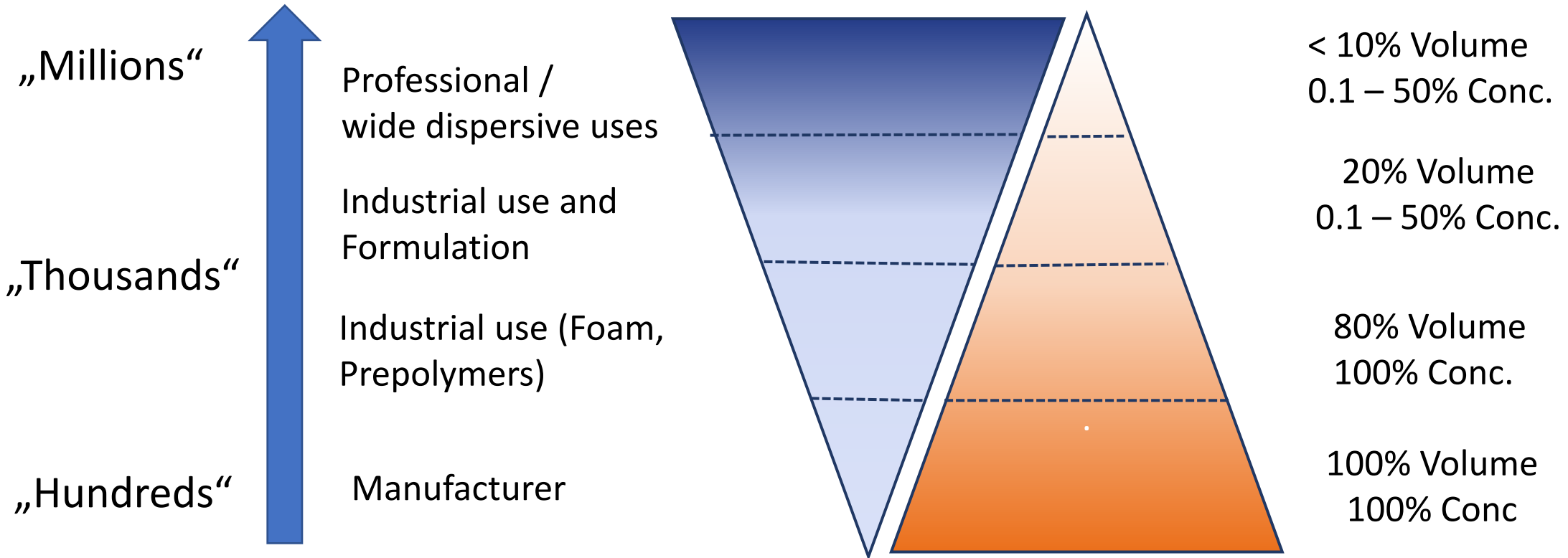
## Polyurethane Adhesives and Sealants





## Number of potentially exposed workers

## Volume and Concentration of Diisocyanates



# Exemptions of Product / Use Combinations



Training of millions of workers in thousands of small companies would be disproportionate



Option of exemption triggers innovation towards safe products by design

- **Polyurethane products have a wide array of applications at SMEs**
  - in construction for sealing, bonding, strengthening, coating, etc.
  - in automotive repair for sealing, bonding, coating, etc.
  - in woodworking, leather and textiles for bonding
  - at the end of complex supply chains
- **For many of these uses behavioral change via training is not required**
  - use of product for short periods of time during a workday
  - low concentration of diisocyanates in the product
  - small quantities of product are used
  - packaging reduces the risk of exposure

# Business Impact



**LOWER MARKET PROFILE** <-  
> TO CANDIDATE LIST &  
AUTHORIZATION



**PRESUMABLY LOWER COST**  
<-> TO AUTHORIZATION  
APPLICATIONS



EXEMPTION IS THE GOAL  
FOR A LARGE VOLUME OF  
**END USES**



MARKETABILITY OF  
REMAINING PU PRODUCTS  
IMPACTED

# Industry pro-active actions on exemptions

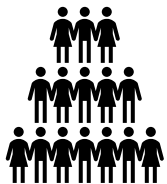
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## 2 draft exemption dossiers are available

- to illustrate added value of exemptions
- to show a workable format
- to demonstrate the inherent safety



Dossier “One Component Foam (OCF)” was shared with authorities and ECHA



Industry is working with well recognised experts in exposure science to **establish rules for assessment of dermal exposure risks**



European OCF manufacturers estimate that > **100.000.000** cans of PU foam are used in the EU each year by more than **500.000** professional end users



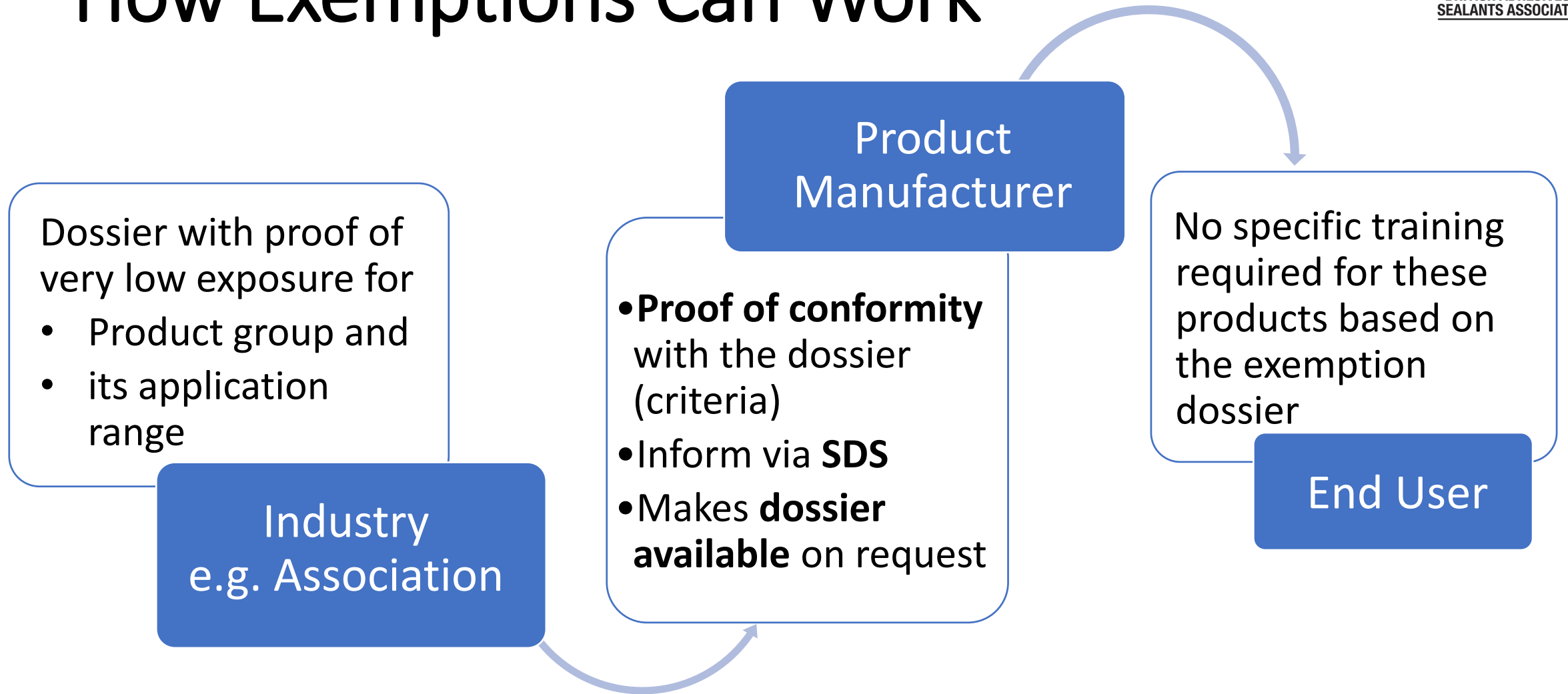
# Criteria for Exemptions

Via EU wide accepted criteria an EU wide level playing field for exemption could be achieved

Industry already started pro-actively to work with scientific institutes and is prepared to engage with all stakeholders

Clearly described and commonly agreed criteria for exemption dossiers to support enforcement

# How Exemptions Can Work



# Downstream communication

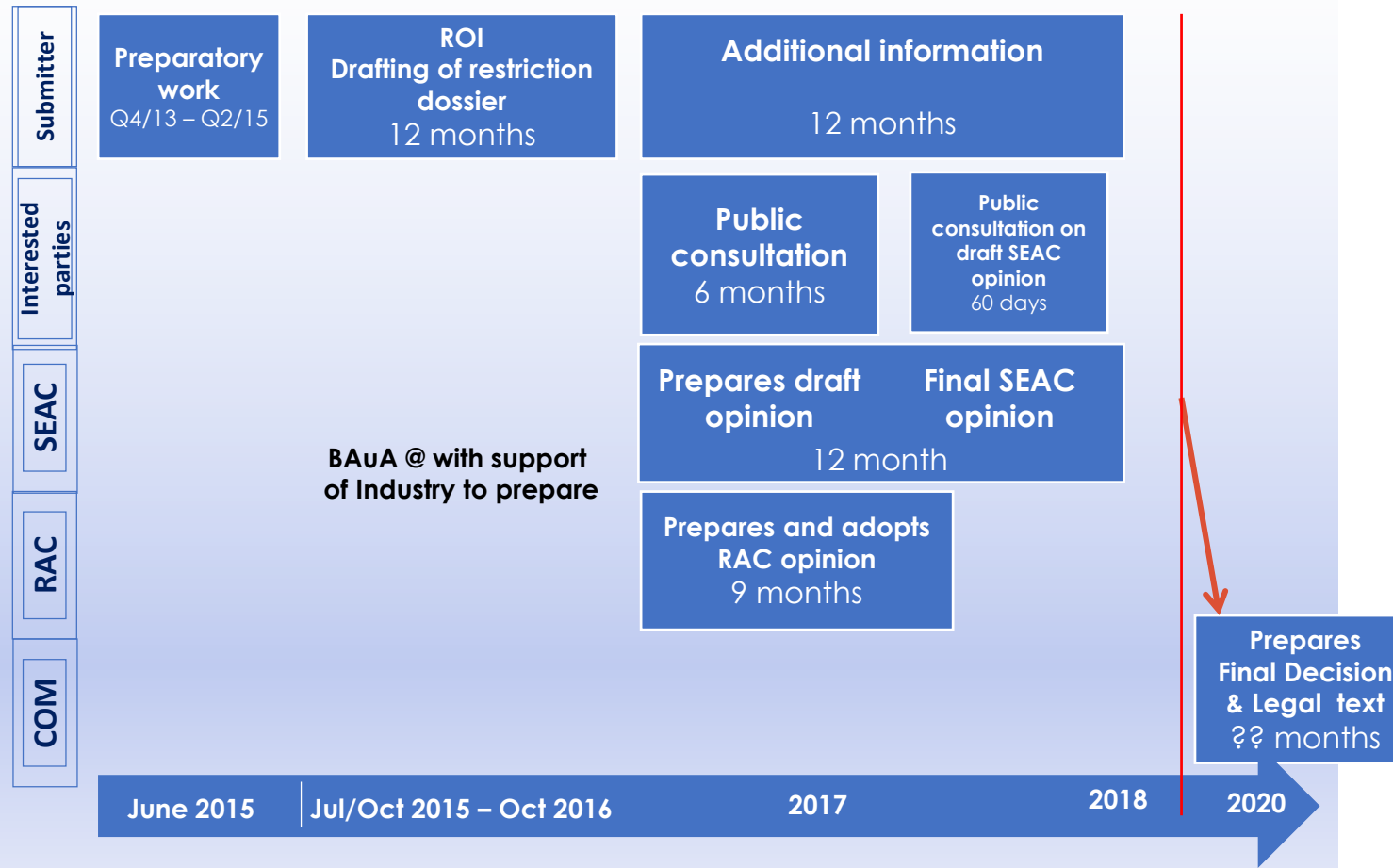
FEICA Leaflet  
Copies available from  
BASA, visit us on stand K5  
for details



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# REACH Process for a restriction





# Thank You!



# Questions?



# BRITISH ADHESIVES & SEALANTS ASSOCIATION



Come and talk to us on Stand K5