



# **CSR, SEA and AofA** for defining the scope of the application

Based on materials and first experiences  
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# Content

- Relevancy of the « Use description »
- BIU/BDU
- Scoping of AofA and SEA
- Benefits of a tiered approach
- Conclusions

Each time from a *manufacturer's* and /or a *DU perspective* (if possible)

# Use(s) identification

## Questions :

### - What **uses to defend**?

#### - Manufacturers and users perspective :

#### - What use is ***critical from an economic and technical viewpoint***

#### - ***Manufacturers*** perspective :

#### - What uses do I want to keep in my portfolio ? And why (e.g. no substitute available)

#### - ***User*** perspective :

#### - What use is not (easily) replacable and the reason why

### - **What's driving** the importance « to defend » the use application ?



# Example : what uses to defend?

## ☞ **Lead compounds :**

- ⇒ Used for Stabilisers in Plastics
- ⇒ Used for Lead Batteries (mainly automotive)

## ☞ **Manufacturer's viewpoint:**

- ✓ **Lead Batteries** : safe application, large volume, high technical performance at low cost and high societal value, maintain manufacturing in the EU instead of import

## ☞ **Users viewpoint:**

- ✓ **Stabilizers** : voluntary phase out given technical performant alternatives available
- ✓ **Lead Batteries** : high technical performance at low cost

**Possible option:** Manufactures request AA for use in batteries while Users ask one for temporally use in Stabilisers untill phase out date

# Conclusions from the « use description »

## HELPS to DEFINE :

1. **What is defensible** from a technical/commercial and medium to long term viewpoint
  - So what Uses to prepare an AA for
2. **Common interests** of manufacturers and users
  - So what parts of the AA could be conducted commonly
3. **What level could best submit** the application for autorisation
  - Manufacturer/importer, formulator downstream user
4. Define the **Broad description of use**
  - How to best describe them
5. Identify the **boundaries** between Uses/Applications
  - How many to defend?
6. Identify **areas of Confidentiality (CBI)**(technical performance, cost, ...)
  - Where can't we work together



**So ensure attention  
time for this step**

# Broad Information of Uses

CRITICAL : from the start.... **define BROAD Information / Description of USES carefully**, considering:

- Need for detail on Technical Specifications
- Balance with CBI
- Can a relevant "Impact Assessment" be performed
- Level of availability of substitutes

**Recommendation:** consider carefully in advance of a PSIS !



SEA-AofA ECHA for defining the scope of the application

# Broad Information of Uses

## Example 1: *for a battery constituent*

- i. *Battery constituent to charge rechargeable batteries* **OR**
- ii. *Battery constituent to charge high density automotive starter batteries allowing cold start and available in > 1 mio t a year*

## Example 2: *for a plating material*

- i. *Substance used in electroplating* **OR**
- ii. *Substance used in electroplating for specialised building applications in high corrosion conditions (sea water,...) compliant with the EC-building standard n° ...*

## Example 3: *for use in building material*

- i. *Substance used in ductile and maleable materials for roofing and gutters* **OR**
- ii. *Substance used in ductile and maleable materials for roofing and gutters of historical buildings to ensure a corrosion resistance level and a life time performance > 100 y*




**Conclusion : BIU** is a key tool to focus and streamline the scoping of the AA and interests of manufactures and DU's

- i. *would **reduce n° of applications** , allow users to group but easily challengeable by third parties and leading to complex and extensive SEA & AofA's (costly and time intensive)*
- ii. ***focus the SEA and AofA's**, focus the third party consultation but increase n° of applications and more splitted Consortia*



## CSR



- ★  **CSR** is usually in the possession of the Manufacturer
- ★  It is recommended that **DU aligns** with the (registered) CSR from the Manufacturers if feasible
- ★  **NEW** : no effects data set for the substance needed in case applicant aligns with RAC DMEL/DNEL recommendation

### Moreover:

- ★ ✓ A CSR for an Authorisation can be "*restricted to the specific use applied for*"
- ★ ✓ If CSR is not available or existing, the DU can submit "*a use specific CSR* "



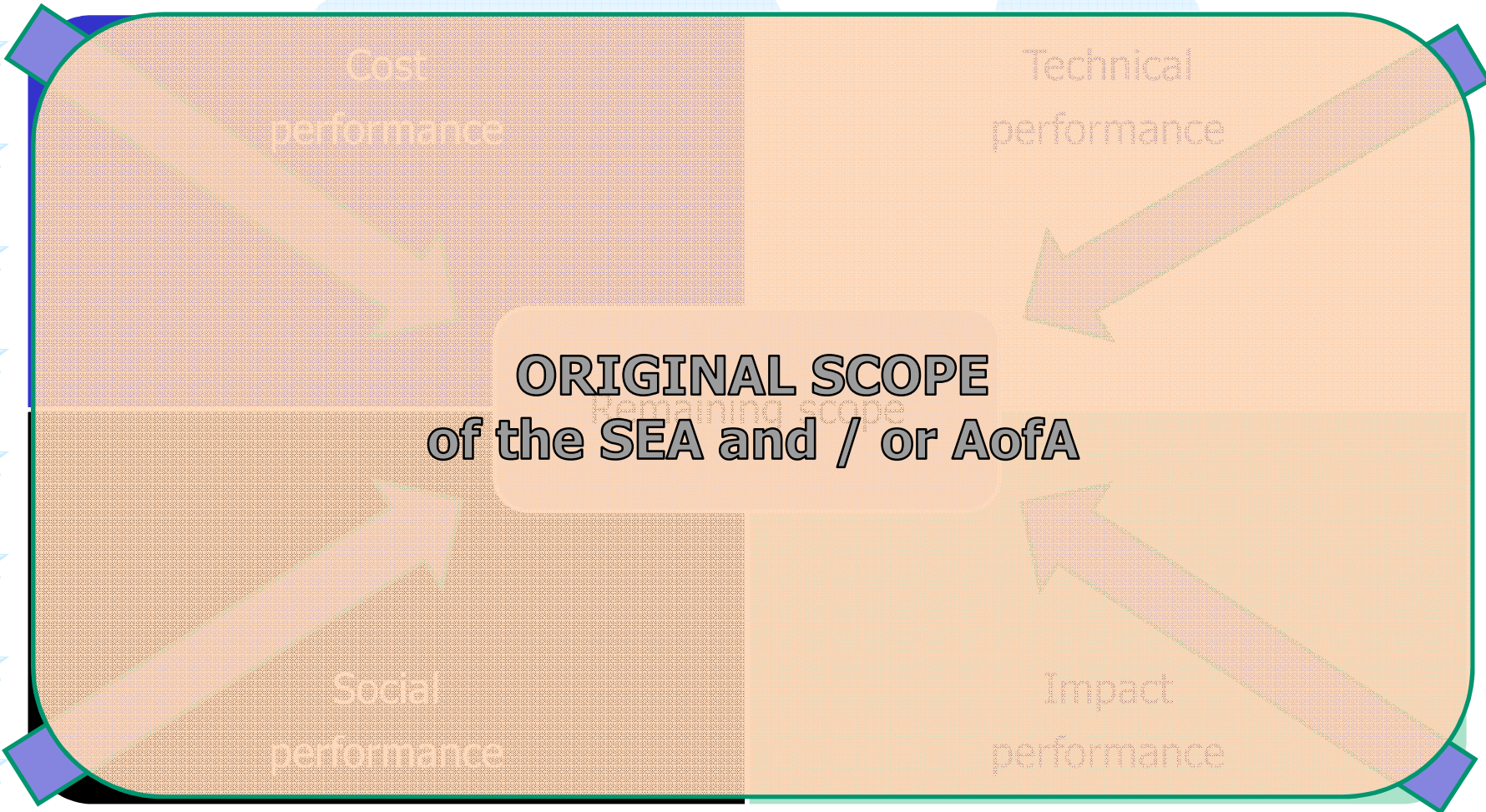


# Scoping the AofA and SEA

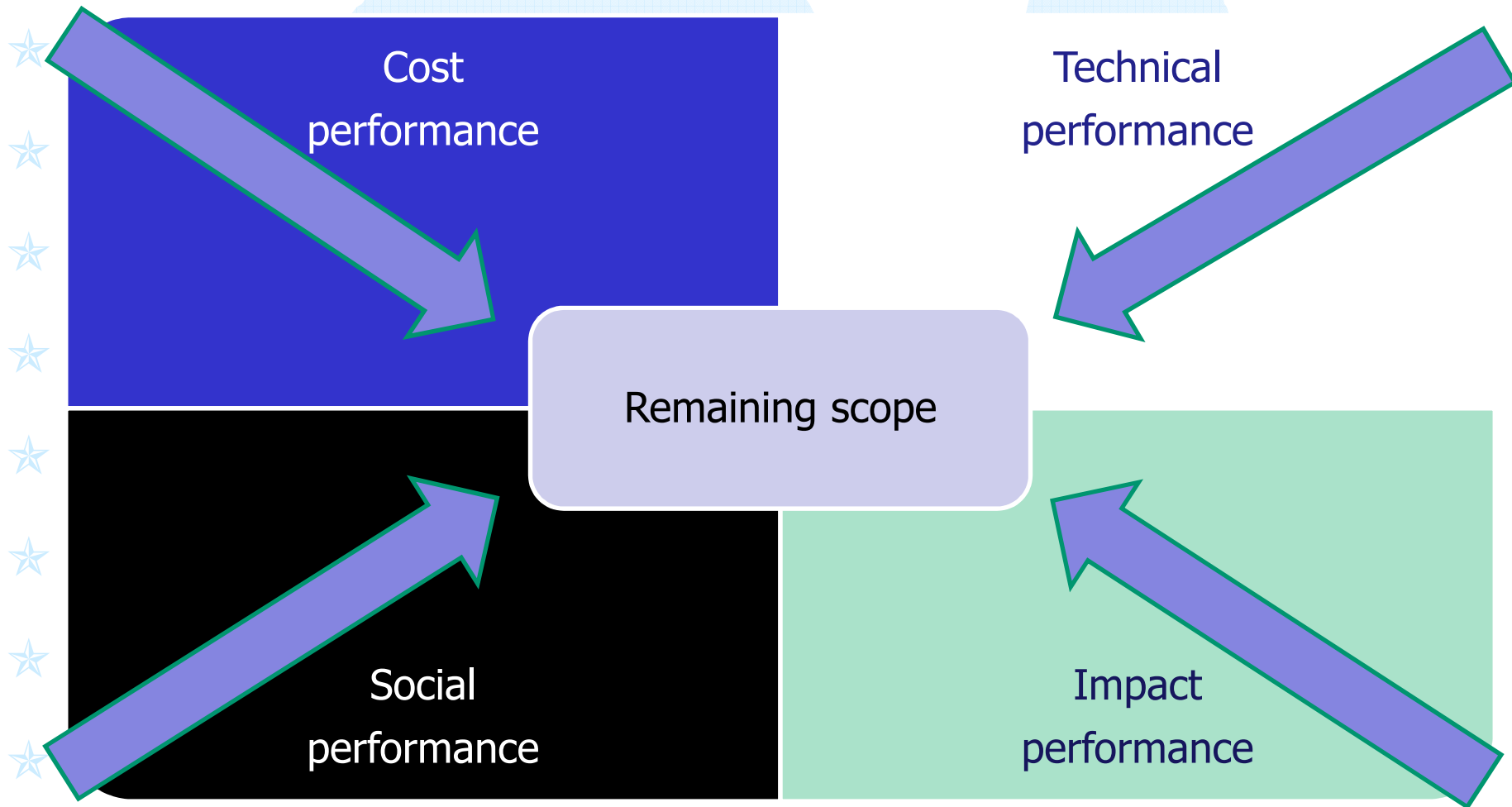
## Walk before running : *the feasibility phase*

- ☞ Start from a « draft » **BIU**
- ☞ Define a **ROBUST baseline scenario** which is **realistic** !
  - ✓ Recognizing the impact of the candidate list or ongoing restrictions
  - ✓ Technical trends and spontaneous occurrence of alternatives
- ☞ Use an **alignment approach** to reduce scoping of AofA or SEA, e.g.
  - ✓ Simple: by identifying possible responses to challenge the AA, eg
    - ✗ Article can be imported without significant cost impact
    - ✗ The product/service will still be made in the EU using an alternative substance
  - ✓ Qualitative/quantitative : alignment approach (see next slide)
- ☞ Most scoping work is **not Confidential** so allows for DU contributions

# Alignment approach to define/reduce scope of AofA or SEA



# Alignment approach to define/reduce scope of AofA or SEA



## Scoping case: *metal catalyst used in steam reforming*

☞ **Steam reforming:** main industrial process for producing hydrogen. It is applied at very large scale for hydrogenation processes in refineries and chemical industry

☞ Estimated 1400 plants worldwide

☞ Currently ***all commercial steam reforming*** catalysts are **metal X-based**.

### Identified **alternatives**:

☞ Ruthenium (Ru) based catalysts

☞ Platinum group metals (PGM) catalysts: platinum, palladium, iridium, rhodium

# Scoping Case: steam reforming

## Technical performance

- ☞ PGM's are more active, more poison resistant and have a longer lifetime

Metal	Cost performance	Other performance
Metal X		
Ruthenium		
Platinum		
Palladium		
Rhodium		

# Scoping Case: steam reforming

## Technical performance

- PGM's are more active, more poison resistant and have a longer lifetime

Metal	Price US (\$/kg)	World production (tpa)
Metal X	17	1,600,000
Ruthenium	4,200	32
Platinum	52,000	252
Palladium	21,000	276
Rhodium	53,000	23

Raw material	Catalyst product
Ru (III) nitrosyl nitrate*	ruthenium oxide*
Oxid. Solid (H272)	Skin Irr. H315
Skin Corr. 1A (H314)	Eye irr. H319
Eye Dam. 1 (H318)	
Met. Corr. 1 (H290)	

## Cost performance and impact assessment

- Others than Ruthenium are not considered feasible alternatives.

## Other performance

- Based on availability...no reasonable substitute seems available

# Case: steam reforming

## Conclusion:

Technically Ru could be used,

- ✓but increased demand will strongly influence market price of the metal.
- ✓Ru-catalysts will quickly become too expensive for a cost-effective operation.

Ru and PGM seem from a hazard point of view acceptable.

Downstream consequences of substitution could be significant:

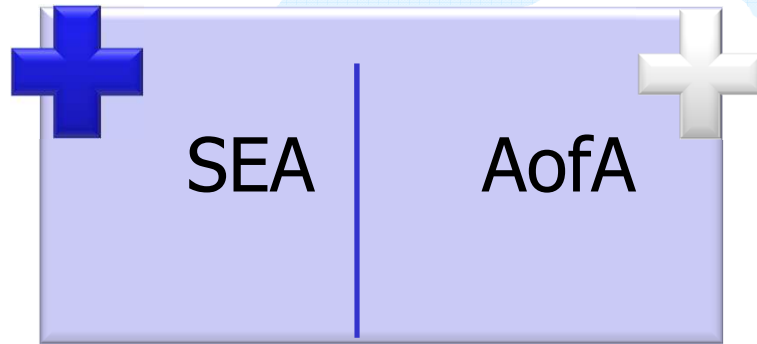
- ✓ Affecting the removal of sulphur
- ✓Technically compromising many downstream refinery processes.

**Currently no suitable alternatives to Metal X based catalysts seems available! => SO a GOOD case to ask an AA for**



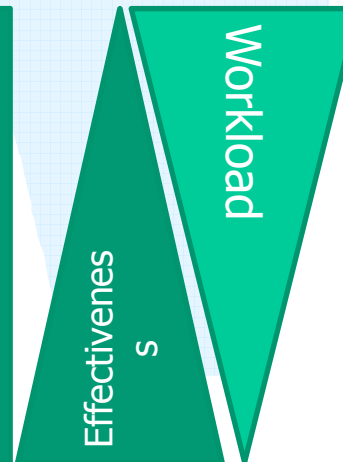
# Conduct SEA-AofA in a Tiered way

## NON TIERED

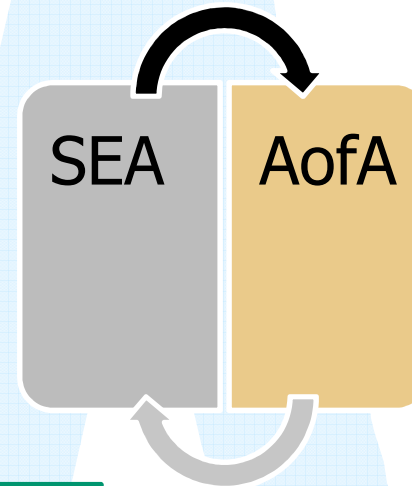


### Metal X catalyst example:

- Gather alternatives
- Assess TP of all alternative
- Gather cost data on X and alternatives
- Compare Impact of X and alternatives
- ...



## TIERED

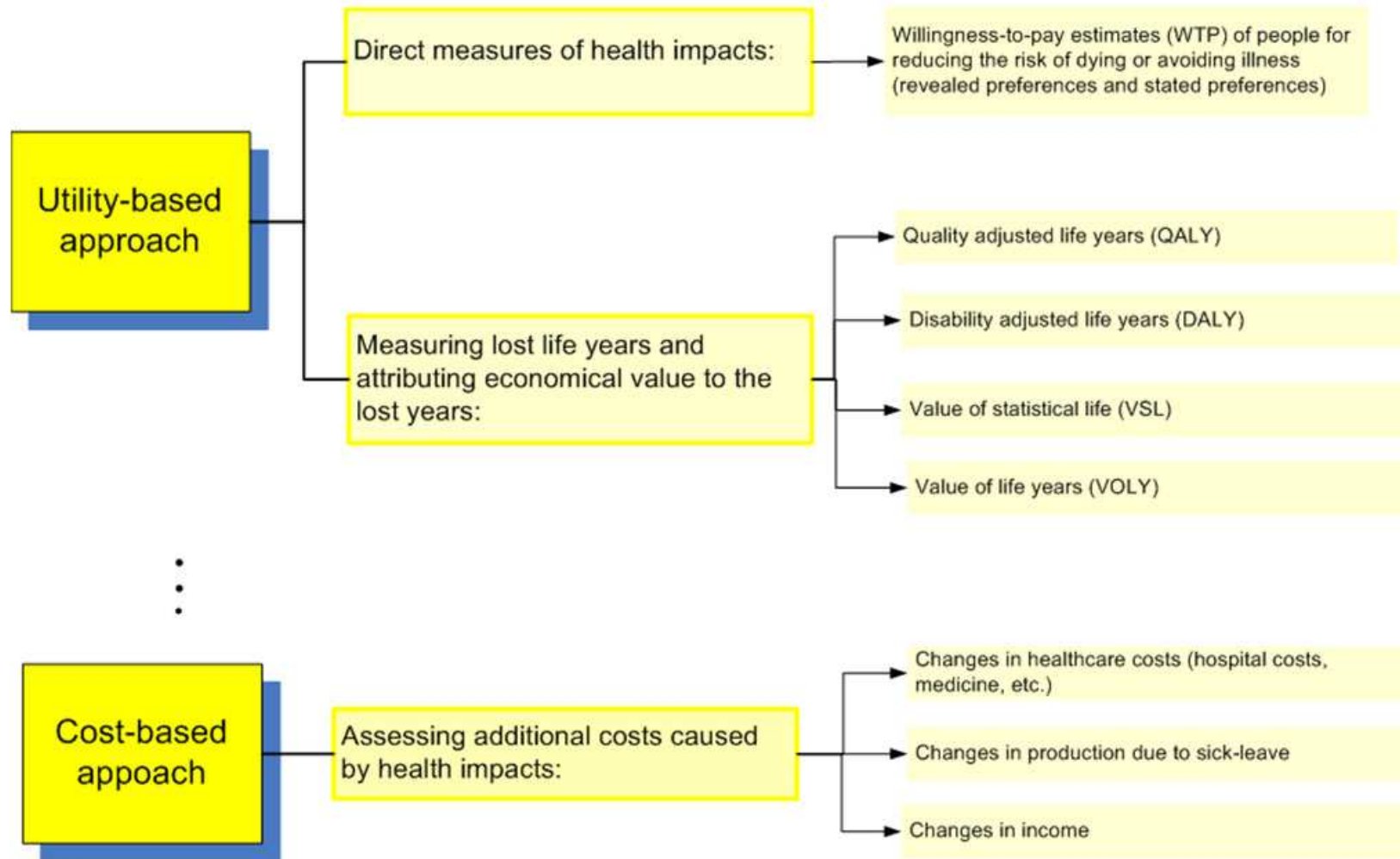


### Metal X catalyst example:






- Define TP
- Compare TF of alternatives
- Compare Impact of X and remaining alternatives
- Gather cost data on X and remaining alternative

# Valuation of HH impacts

Choose your SEA HH impact assessment concept based on **the most appropriate model** for the remaining options



# Conclusions

- ★  Define the « **Technical performance** » as precise as possible given it guides the BIU, the CBI area's, collaboration potential, ...
- ★  Conduct your **BIU in a tiered refinement** mode together with DU's to achieve the right balance between CBI/workload
- ★  **Scoping of AofA's and SEA's** allows focuss on the real drivers
- ★  **Tiered and interactive approaches** in SEA and AofA increases effectiveness and avoid extensive data gathering and CBI and allows for refining the BIU
- ★  **Choosing an optimal SEA-impact model** for remaining alternatives makes the outcome easier to interpret

**STRIVE FOR KISN't**  
(Keep It Simple but **Not** sTupid)