



# Cost of Authorisation to EU Industry

Helsinki, 8 July 2016

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Se Al Cu Ni Pb Sn Zn Au Ag Pt Sb W Be Si Cr Co Mo Ge V Mn Ir Ru Rh Ta

# Content

What are the **cost drivers**?

The **generic costs** of an application for authorisation: how does it evolve?

The impact of the **organizational level**

**Integrating SEA and AoA** helps defining focus and decreasing costs

Level of **refinement needed**

**Repetitive AfAs** needed for a single use

**Outstanding challenges** that impact the cost of an application

**Conclusions and recommendations**

# The cost of authorisation to EU industry

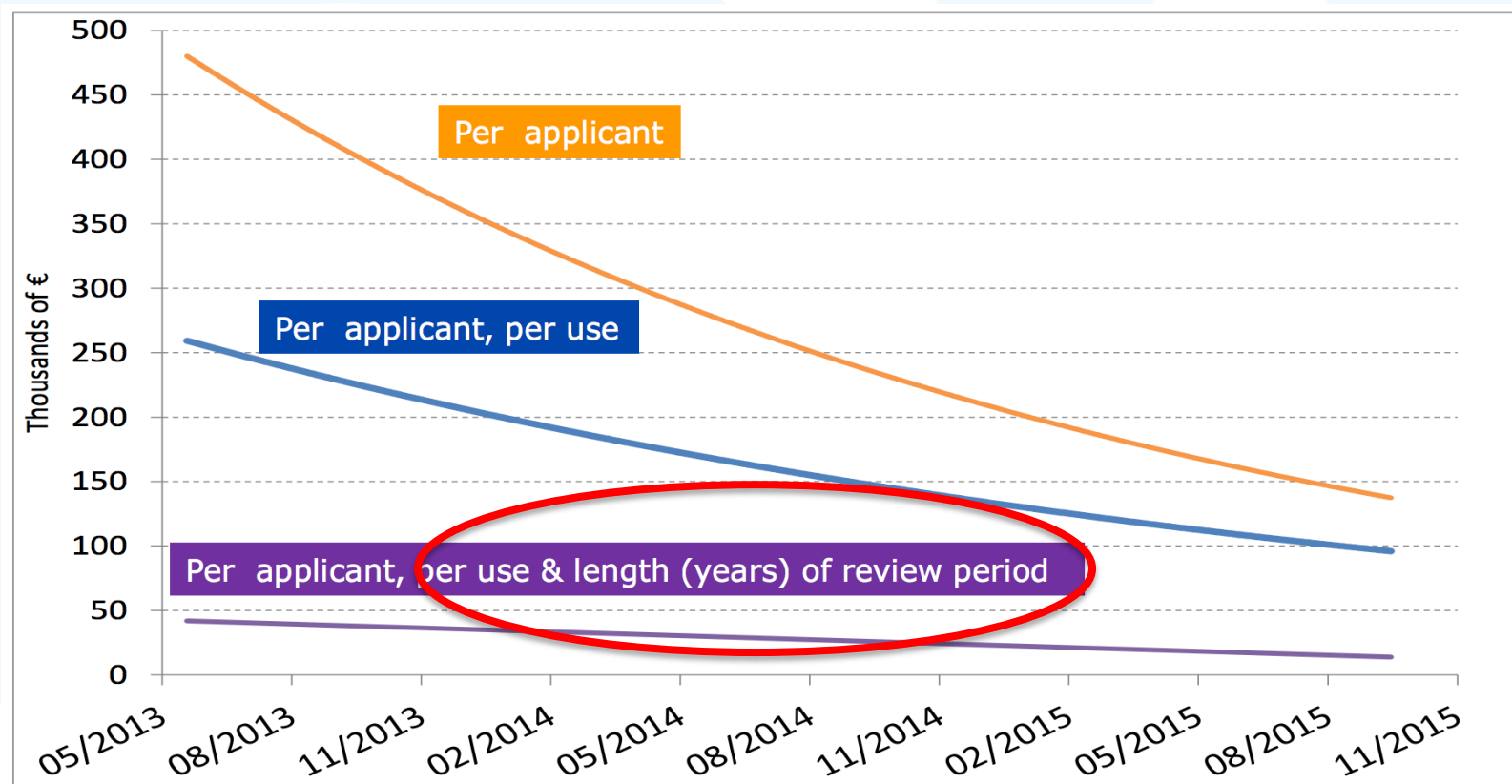
## What are *the cost drivers*?

- Data collection (time, effort, ...)
- Consultancy (for SEA and AoA)
- Number and type of uses covered
- Organizational level (management model, joint or single, need for a trustee...)
- Technical approach (integration AoA & SEA) and level of focus
- Need for refinement
- Authorisation fees



# The cost of Authorisation *In general*

**ECHA inventory:** integrated costs for authorisation (for AfA submission)



# The cost of Authorisation

**Trend** seems declining.....

Is this realistic or not?

Probably NOT:

- Non-representativeness of the first substances
- Relatively simple uses
- No need for refinement

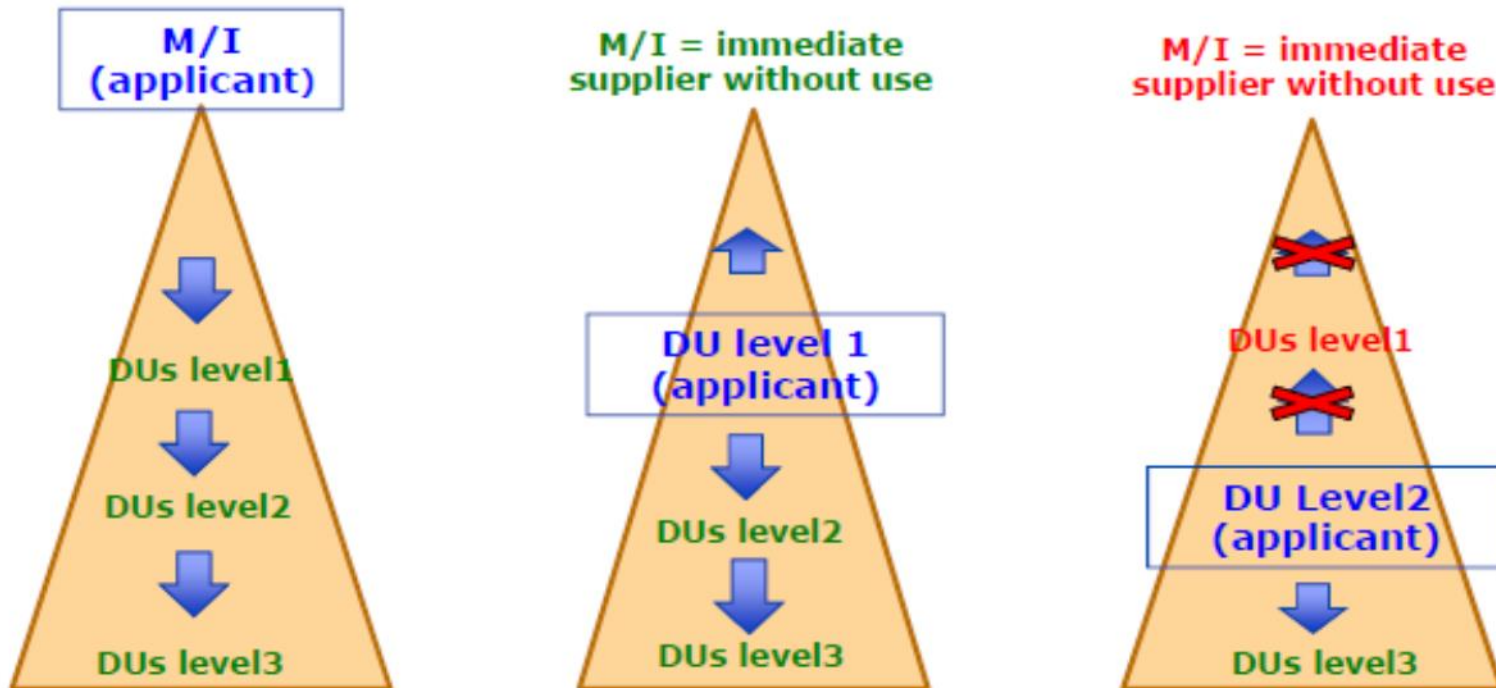
Certainly helped reducing costs:

- More focused SEAs and AoAs
- More experienced consultancy



# Factors that impact the costs of Authorisation

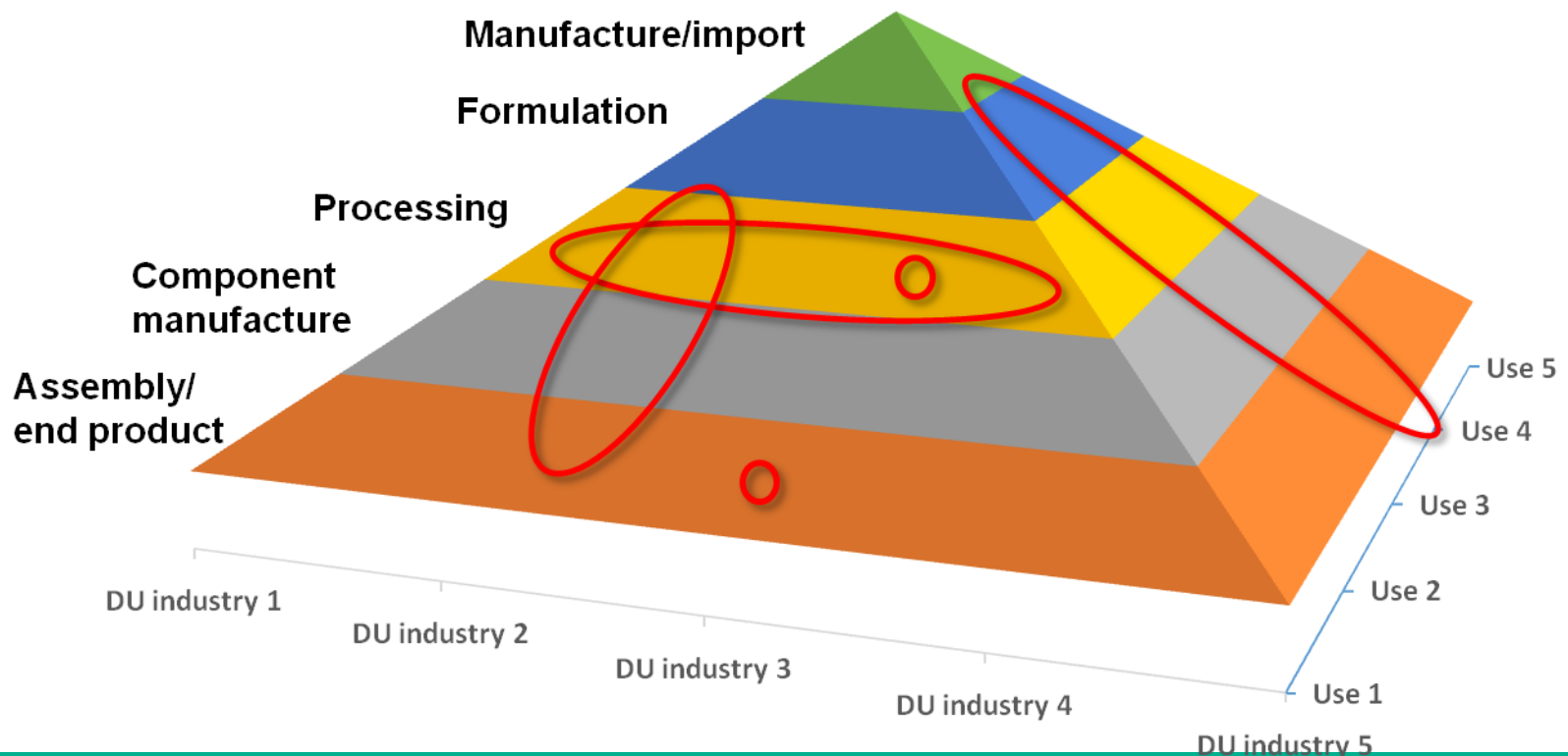
**Organizational level** : sharing the cost over the supply chain



# Factors that impact the costs of Authorisation: *Organizational level*

**Organizational level** : sharing the cost over the supply chain

- Supply chain cost or cost for a user depends on the organizational level
- Managerial costs varied between: < 5000 € to > 1 mio €



# Factors that impact the costs of Authorisation: *Organizational level*

## **Review Period** for comparable cases\*:

- Upstream functional plating cases : 4 or 7 years
- Downstream functional plating cases: 7 or 12 years

### **Review period** defined on the basis of:

- Relevancy and robustness of AoA data
- Clarity and level of remaining exposure
- Relevancy and robustness of the SEA data



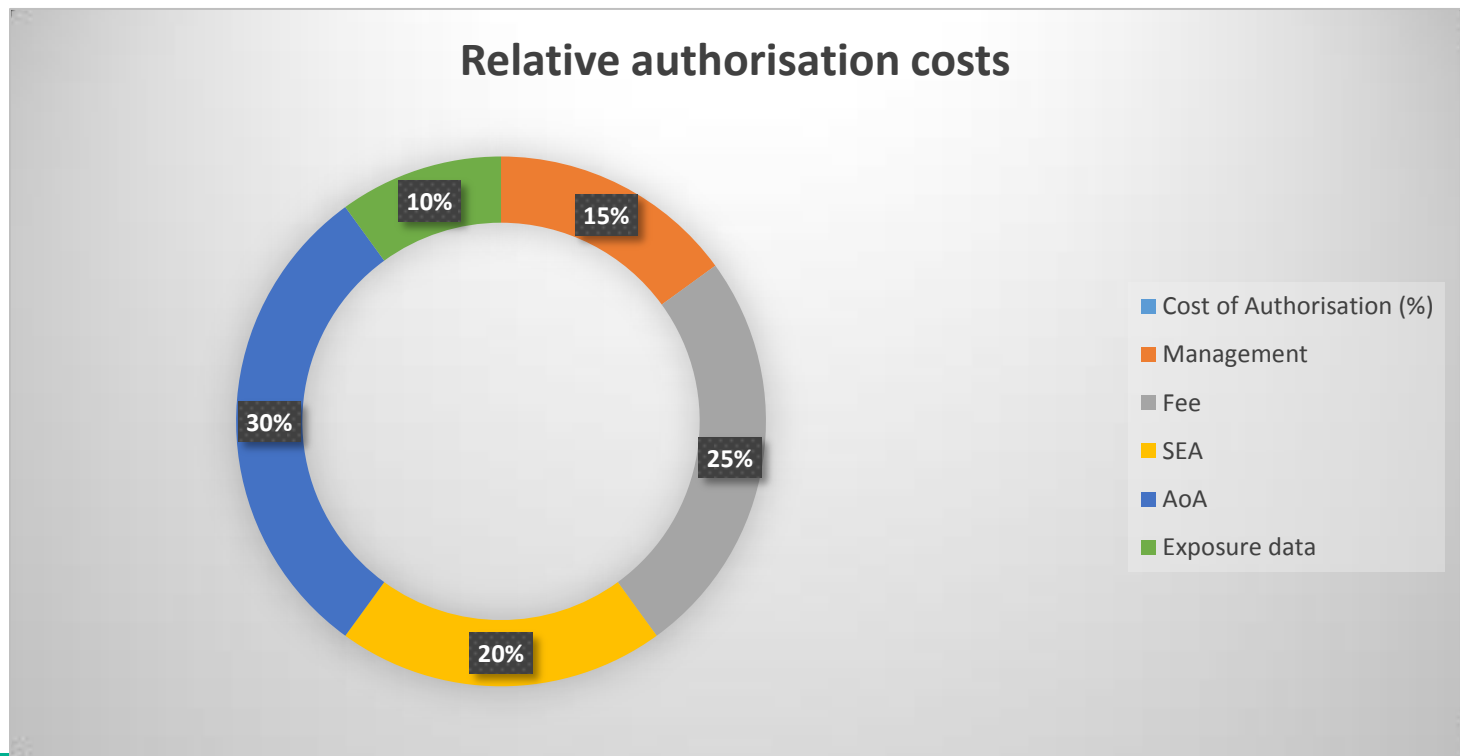
\*based on todays experience.



# Cost of Authorisation for the EU Industry

## Relative Authorisation costs for a couple of cases in the metal sector:

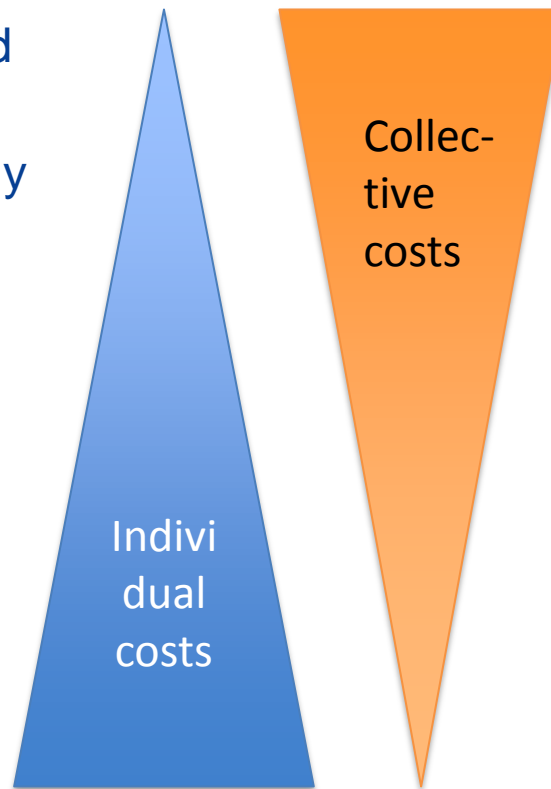
- SEA and AoA cover half of the costs
- Management costs and fee around 40 %
- Remainder for the collection of exposure evidence



# Factors that impact the costs of Authorisation: *Organizational level*

## **UPSTREAM** application:

- Good cost sharing
- Knowledge/workload sharing
- Higher cost/granted y



- Better cost/granted y
- No sharing of knowledge or workload
- High individual costs

## **DOWNSTREAM** application:

# Factors that impact the costs of Authorisation: *Level of integration of the SEA-AoA assessment:* *example of metal catalyst used in steam reforming*

**Steam reforming** is the 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 on AoA: steam reforming



## Technical performance

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

Metal	Cost performance	Other performance
Metal X		
Ruthenium		
Platinum		
Palladium		
Rhodium		

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

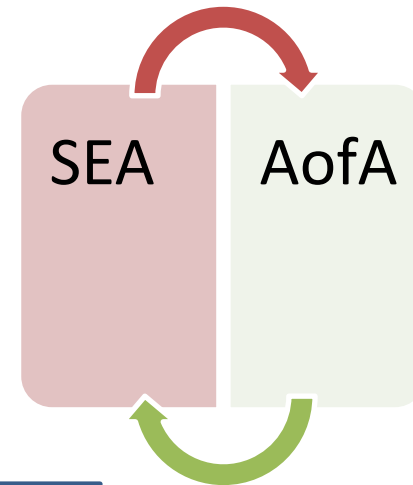
- Based on availability...no reasonable substitute seems available

# Conduct SEA-AoA in a Tiered way

## NON TIERED

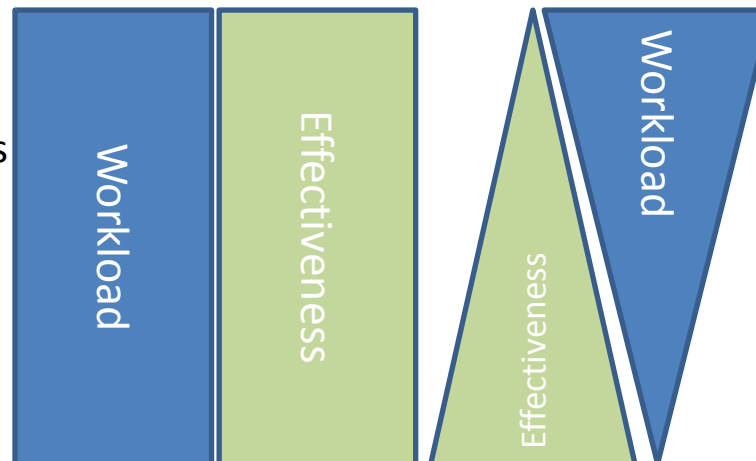


## TIERED



### Metal X catalyst example:

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



### Metal X catalyst example:

- Define Technical Performance (TP)
- Compare TP of alternatives
- Compare Impact of X and remaining alternatives
- Gather cost data on X and remaining alternative

# Factors that impact the costs of Authorisation: *Level of refinement needed*

## SEA assessments made **on Excess Cancer Risk**

- Applicants therefore focus usually **on Workplace exposure**:
  - levels
  - n° exposed workers
  - Exposure time
- Often they do not focus on **other factors that define the cost to society** given assumed being low: *example Man via the Environment*
- See example
- Suggestion: conduct a **sensitivity analysis** of scenario and parameters that impact the excess cancer risk and refine the assessment with real measurements when needed.



PS a program for MvE refinement may cost up to > 250 k€ when based on monitoring evidence !!!

# Factors that impact the costs of Authorisation: *Level of refinement needed*

## Example of Man via the Environment assessment in a recent AfA case on Chromium trioxide use for Functional Chrome Plating

Estimated additional statistical fatal cancer cases, based on 40/70 years of exposures, RP applied for, 1 year of exposure)

	Exposure duration per day (h)	Exposure 8h adjusted TWA ( $\mu\text{g}/\text{m}^3$ )	Excess lung cancer risk	Number of exposed people	Estimated statistical fatal cancer cases (years of exposure)		
					40 y	12 y	1y
Workers – Combination of WCS	<1	0.25	0.001	4392	4.39	1.32	0.10
	1-3	0.75	0.003	2062	6.19	1.86	0.16
	4-6	1.5	0.006	2289	13.73	4.12	0.34
	6-8	2	0.008	7608	60.86	18.26	1.52
	Not regularly exposed	0.25	0.001	6577	6.58	1.97	0.16
<b>Workers total</b>				22928	<b>91.75</b>	<b>27.53</b>	<b>2.29</b>
	<b>Exposure 24h (<math>\mu\text{g}/\text{m}^3</math>)</b>				<b>70 y</b>	<b>12 y</b>	<b>1 y</b>
Man via environment - Local	$2.85 \times 10^{-6}$		$8.27 \times 10^{-5}$	10,000 x 1,590 sites = 15,900,000	<b>1314.93</b>	<b>225.42</b>	<b>18.78</b>
Man via environment - Regional	Not relevant						
<b>Total</b>					1406.68	252.94	21.08

# Factors that impact the costs of Authorisation: *Number of repetitive AfAs for the same use*

Authorisations are applied on a **”substance basis”**

However, some “uses” are **“multi-substance based”** and may even have a low control level on what substances they receive.

This could lead to **“multiple authorisation needs”** for a single use resulting in increased costs level

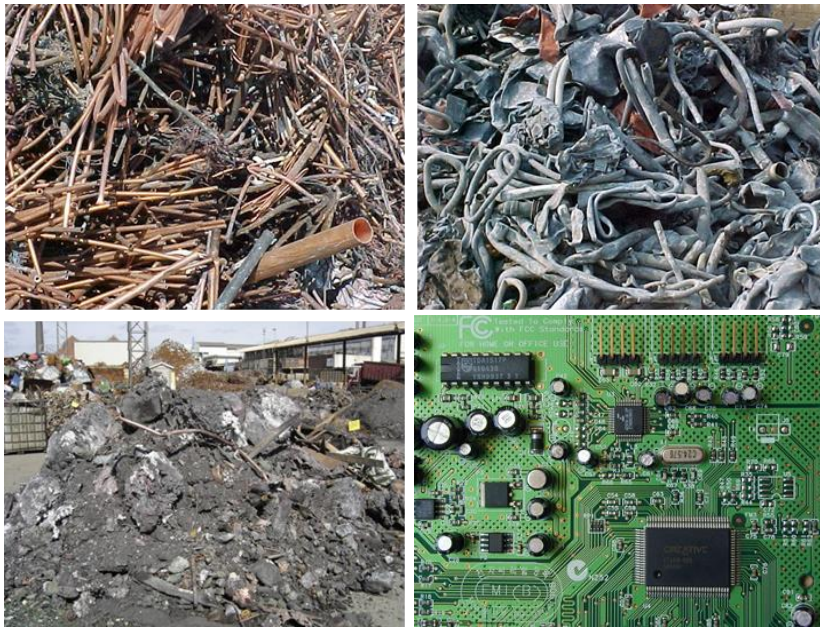
**Example:** mixing as a use in the refining sector (End of Life recycling)





# Factors that impact the costs of Authorisation: *Number of repetitive AfAs for the same use*

**Example:** mixing as a use in metal recycling of End of Use



Recent study by Mike Holland EMRC:

Multiple authorisations for mixing as a use  
up to 20 different substance/use combinations  
due to the variable nature of the input materials

Total costs estimated in the order of

€0.5 to 2 mio € / company

## Factors that impact the costs of Authorisation: *challenges in the cost/benefit quantification*

**Uncertainty, bias or inadequate data decreases the review period** and hence increase the costs for submission.

They are probably still somewhat related to the “**novelty**” the **SEA** scheme and include in particular:

- *Defining the Non-Use scenario:*
  - The most cost-effective scenario is not always chosen
- *Cost estimates through “job/employment-losses”*
  - Rather than “profit loss” or temporally employment loss
- *Lack of “discounting”*
  - Making the assessments “too worst case”
- ...

# Novelty.



## Conclusions

and how to improve the relevancy of the SEA while decreasing the cost?

# Conclusions

**Authorisation scheme** is still new but trends on costs of EU industry becomes clearer with experience.

The overall **cost/applicant is declining** (up to the 100 k € range) but the representativity of the documented cases/costs is unsure

Costs for industry should not be expressed as total cost but at **cost / year granted !** (to encourage the quality of the applications.

Level of organization, quality and robustness of the exposure data/SEA/AOA determine the **costs and Review Period**

The level of refinement is another cost driver but **cost savings** (while increasing the relevancy/focus can be made by aligning of integrating SEA and AoA

Clarifying **outstanding challenges on methods and scenarios** (how to account for Job-losses, and the Man via the Environment, ...) can reduce the costs while increasing the relevancy of the SEA assessments.

Applicants should conduct an **integrated screening AoA/SEA followed by a sensitivity analysis** to define the focus of the assessment and need for refinement.