Cost of Authorisation to EU Industry

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By Hugo Waeterschoot
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 today's 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

**DOWNSTREAM** application:
- Better cost/granted y
- No sharing of knowledge or workload
- High individual costs
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

<table>
<thead>
<tr>
<th>Metal</th>
<th>Cost performance</th>
<th>Other performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metal X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ruthenium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platinum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palladium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rhodium</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Raw material</th>
<th>Catalyst product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ru (III) nitrosyl nitrate*</td>
<td>ruthenium oxide*</td>
</tr>
<tr>
<td>Oxid. Solid (H272)</td>
<td>Skin Irr. H315</td>
</tr>
<tr>
<td>Skin Corr. 1A (H314)</td>
<td>Eye Irr. H319</td>
</tr>
<tr>
<td>Eye Dam. 1 (H318)</td>
<td></td>
</tr>
<tr>
<td>Met. Corr. 1 (H290)</td>
<td></td>
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</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Workers – Combination of WCS</th>
<th>Exposure duration per day (h)</th>
<th>Exposure 8h adjusted TWA (µg/m³)</th>
<th>Excess lung cancer risk</th>
<th>Number of exposed people</th>
<th>Estimated statistical fatal cancer cases (years of exposure)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;1</td>
<td>0.25</td>
<td>0.001</td>
<td>4392</td>
<td>40 y 12 y 1y</td>
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<tr>
<td></td>
<td>1-3</td>
<td>0.75</td>
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<td>2062</td>
<td>4.39 1.32 0.10</td>
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<td>4-6</td>
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<td>0.006</td>
<td>2289</td>
<td>6.19 1.86 0.16</td>
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<tr>
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<td>6-8</td>
<td>2</td>
<td>0.008</td>
<td>7608</td>
<td>13.73 4.12 0.34</td>
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<tr>
<td></td>
<td>Not regularly exposed</td>
<td>0.25</td>
<td>0.001</td>
<td>6577</td>
<td>6.58 1.97 0.16</td>
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<tr>
<td>Workers total</td>
<td></td>
<td></td>
<td></td>
<td>22928</td>
<td>91.75 27.53 2.29</td>
</tr>
<tr>
<td></td>
<td>Exposure 24h (µg/m³)</td>
<td>2.85 ×10⁻⁶</td>
<td>8.27 ×10⁻⁵</td>
<td></td>
<td>70 y 12 y 1y</td>
</tr>
<tr>
<td>Man via environment - Local</td>
<td></td>
<td>10,000 x 1,590 sites = 15,900,000</td>
<td>1314.93</td>
<td></td>
<td>252.94 18.78</td>
</tr>
<tr>
<td>Man via environment - Regional</td>
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<td>Not relevant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td>1406.68</td>
<td>252.94 21.08</td>
</tr>
</tbody>
</table>
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” of 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”

- ...
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.