WHAT ARE THE COSTS AND BENEFITS OF AUTHORISATION: RESULTS OF THE STUDY ON THE IMPACTS OF AUTHORISATION

Stock-taking conference on the implementation of REACH authorisation

14\textsuperscript{th} November 2017

Presentation by Rohit Mistry (eftec)
OVERVIEW

1. Costs
2. Benefits
3. Summary
# COSTS

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>European Chemicals Agency</td>
</tr>
<tr>
<td>2</td>
<td>Member State Competent Authorities</td>
</tr>
<tr>
<td>3</td>
<td>European Commission</td>
</tr>
<tr>
<td>4</td>
<td>Third parties</td>
</tr>
<tr>
<td>5</td>
<td>Industry</td>
</tr>
</tbody>
</table>
Based on 2014 - 2016

~€3m per year

Authorisation application opinion-making 50%
Annex XIV recommendation 14%
Annex XV dossier preparation and candidate listing 34%
Authorisation-related RMOAs 2%
MEMBER STATE COMPETENT AUTHORITIES

~€4.4m per year

- REACH authorisation policy issues 35%
- REACH Committee meetings 14%
- RAC/SEAC non-plenary activities 27%
- RAC/SEAC plenary activities 8%
- MSC meetings 10%
- Compiling Annex XV dossiers 4%
- Undertaking RMOAs 2%

eftec: Results of the study on the impacts of authorisation
~€1.1m per year

Based on 2016

Policy development: 23%
RM OA and SVHC Roadmap: 17%
ECHA recommendations & Annex XIV amendments: 10%
Authorisation decisions: 50%
COSTS TO THIRD PARTIES: PUBLIC CONSULTATION SUBMISSIONS

Public consultation on the inclusion of a substance in the Candidate List

- Trade union
- NGO
- MS CA
- Industry or trade association
- Individual
- Governmental org.
- Company
- Academic institution

2008-2016: 3591 submissions, 196 substances

Public consultation on the inclusion of an SVHC in Annex XIV

- Trade union
- NGO
- MS CA
- Industry or trade association
- Individual
- Governmental org.
- Company
- Academic institution

2009-2016: 3088 submissions, 187 substances

Public consultation on AfAs

- Trade union
- NGO
- MS CA
- Industry or trade association
- Individual
- Company
- Academic institution

2013-2016: 1128 submissions, 21 substances
COSTS TO THIRD PARTIES: PUBLIC CONSULTATION

Public consultation on the inclusion of a substance in the Candidate List

<table>
<thead>
<tr>
<th>Time taken to produce response</th>
<th>1-5 days</th>
<th>6-10 days</th>
<th>11-40 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>42%</td>
<td>25%</td>
<td>33%</td>
</tr>
</tbody>
</table>

Public consultation on the inclusion of an SVHC in Annex XIV

<table>
<thead>
<tr>
<th>Time taken to produce response</th>
<th>&lt;1 day</th>
<th>1-5 days</th>
<th>6-10 days</th>
<th>11-40 days</th>
<th>&gt;40 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>6%</td>
<td>44%</td>
<td>13%</td>
<td>31%</td>
<td>6%</td>
</tr>
</tbody>
</table>

Public consultation on AfAs

<table>
<thead>
<tr>
<th>Time taken to produce response</th>
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<th>1-5 days</th>
<th>6-10 days</th>
<th>11-40 days</th>
<th>&gt;40 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>12.5%</td>
<td>25%</td>
<td>12.5%</td>
<td>37.5%</td>
<td>12.5%</td>
</tr>
</tbody>
</table>
**INDUSTRY: COMPLIANCE COSTS**

- 71% of survey respondents (n=45/63) stated that they had incurred some form of compliance cost

**Number of respondents (n=45) that incurred the following types of compliance costs:**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number</th>
<th>Average cost per company</th>
<th>Prevalent cost range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Familiarisation with REACH authorisation requirements</td>
<td>40</td>
<td>€18,300 - €32,900</td>
<td></td>
</tr>
<tr>
<td>Providing information to allow safe use of an article</td>
<td>10</td>
<td></td>
<td>€100,000 - €200,000 (50%)</td>
</tr>
<tr>
<td>Updating an eSDS</td>
<td>9</td>
<td></td>
<td>€501 - €10,000 (55%)</td>
</tr>
<tr>
<td>Complying with reporting obligations in authorisation decision and preparing review report</td>
<td>9</td>
<td></td>
<td>€1,001 - €50,000 (77%)</td>
</tr>
<tr>
<td>Notifying DUs of an authorised use</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Updating a registration dossier following AfAs</td>
<td>8</td>
<td></td>
<td>€1,001 - €50,000 (62%)</td>
</tr>
</tbody>
</table>
INDUSTRY: COSTS OF SUBSTITUTION

**One-off investment costs to implement an alternative (substance or process)**
- €1-€10 million: 9%
- €11-€50 million: 13%
- >€100 million: 0%
- <€1 million: 78%

**Annual net operating costs to using an alternative (substance or process)**
- <€100 000 per year: 61%
- €100 000 - €1 million per year: 28%
- €1-€10 million per year: 5%
- €11-€50 million per year: 6%
- >€100 million per year: 0%

n=32
n=18
INDUSTRY: COSTS OF SUBSTITUTION

Annual spending on substitution activities

- €10 - €100 million per year: 5%
- €1 - €10 million per year: 5%
- €100,001 - €1 million per year: 18%
- €50,001 - €100,000 per year: 23%
- €10,001 - €50,000 per year: 28%
- <€1,000 per year: 5%
- >€100 million per year: 0%

n=43
81% (n=35 out of 43) of survey respondents indicated that authorisation has had an impact on their annual R&D, innovation, investment spending.
INDUSTRY: COSTS TO APPLY FOR AUTHORISATION

Notional total cost - per applied for use

Notional total costs include:
- Direct costs
- Fees
- Internal staff time

Graph showing the notional total cost (€ 000) from 2013 to 2016.
INDUSTRY: COSTS TO APPLY FOR AUTHORISATION

Reported mean notional total application costs per use and applicant

By supply chain position

<table>
<thead>
<tr>
<th>Position</th>
<th>Mean Cost (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>310k</td>
</tr>
<tr>
<td>Importer</td>
<td>302k</td>
</tr>
<tr>
<td>Downstream user</td>
<td>196k</td>
</tr>
<tr>
<td>Manufacturer/Importer</td>
<td>179k</td>
</tr>
</tbody>
</table>

Based on: ECHA data for 2013-2016

By company size

<table>
<thead>
<tr>
<th>Size</th>
<th>Mean Cost (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large</td>
<td>221k</td>
</tr>
<tr>
<td>Medium</td>
<td>156k</td>
</tr>
<tr>
<td>Small</td>
<td>112k</td>
</tr>
<tr>
<td>Micro</td>
<td>37k</td>
</tr>
</tbody>
</table>

Based on: ECHA data for 2013-2016

- Post submission costs - Mean costs to applicants in the opinion-making phase: ~€17k
40% (i.e. 23 out of 57) of survey respondents indicated that they had improved risk management of SVHCs as a result of the authorisation process.
# BENEFITS OF REACH AUTHORISATION

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Reduction in exposure to SVHCs</td>
</tr>
<tr>
<td>2</td>
<td>Reduction in emissions of SVHCs to the environment</td>
</tr>
<tr>
<td>3</td>
<td>Awareness and adoption of alternatives (to SVHCs)</td>
</tr>
<tr>
<td>4</td>
<td>Benefits of substitution</td>
</tr>
<tr>
<td>5</td>
<td>Better information</td>
</tr>
<tr>
<td>6</td>
<td>Other benefits</td>
</tr>
</tbody>
</table>
REDUCTION IN EXPOSURE & EMISSIONS

1. Improvements in RMMs where SVHCs are still be used

2. Substitution away from an SVHC

3. Avoided exposure and emissions within the EU due to closing and/or relocating EU production sites
BENEFITS OF SUBSTITUTION - TOO EARLY TO SAY?

1. Sales of alternative

2. Employment using an alternative

3. Exposure and emissions of SVHCs

Net benefit?

77% of survey respondents who substituted identified REACH authorisation as the main driver

23% of survey respondents who substituted, attributed this to other factors

Net benefit?
BETTER INFORMATION AND COMMUNICATIONS

1. Use specific information on exposure and risk management

2. Suitability of possible alternatives

3. Whether society is better or worse off with continued use?

Improved supply chain communications
SUMMARY

- Costs to EU public authorities ~€8.5 million / year
- Costs to EU applicants ~€9 million / year (based on 50 uses per year)
- Costs of substitution ~ One off costs <€1million per company (mean ~€1.5million)
- Other compliance costs difficult to estimate - Costs of additional RMMs associated with these applications might add another €7million / year
- Further thoughts required to mitigate/minimise some of the costs to third parties - Are all submissions relevant and/or effective?
- Benefits from reductions in exposure and emissions of SVHCs - Still a lack of data necessary to quantify and monetise these benefits
- Clear evidence of substitution - but too early to judge the net impact of substitution
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