



# Enhancing European Efforts Towards Informed Substitution: Findings and Reactions to a European Union Capacity Needs Assessment

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# Speakers and Panelists



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Control

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# **Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives: Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH**

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# Substitution – A Long Standing Approach in the EU

Examples:

- Member state legislation
- EU legislation
- 1987 Montreal Protocol, the 2001 Stockholm Convention, and the United Nation's Strategic Approach to International Chemicals Management
- REACH

# Substitution & REACH

- Substitution: a key risk management strategy within REACH
  - Centers around the use of alternatives assessment/analysis of alternatives (AoA)
    - Substances of very high concern (SVHCs) subject to Authorisation require an AoA
    - Restriction proposals undergo a Socio Economic Impact evaluation that contains a similar AoA

# Substitution Capacity Study: Purpose

- Review of EU authority and Member State capacity to support the identification, evaluation, and adoption of safer alternatives
  - Particular interest in the use of AoA
- Considered a “scoping evaluation”

# Substitution Capacity & Capacity Needs: Assessment Approach

- **Surveys**
  - MS REACH Competent Authorities (N=16)
  - Industry Representatives (N=107)
  - Industry Consultants (N=20)
- **Interviews with stakeholders**
  - MS REACH Competent Authorities
  - Industry Consultants
  - NGOs
  - Innovation Institutes
- **Reviews of informative authorization applications and restriction proposals**



# 1. Substitution is Happening – EU Legislation Key Driver

- **Substitution is happening: implemented substitutes for hazardous substances in the last 10 years**
  - 81% (N=79) of industry survey respondents
  - 59% (N=10) of industry consultant survey respondents
- **REACH stated as the dominant driver of substitution in the EU (among all 3 stakeholders surveyed)**
  - Industry reps & consultants: Candidate List key regulatory process that initiates interest in and search for substitutes
  - The Annex XIV REACH authorisation list was also noted as a key driver
  - Other regulations also a driver

## 2. Principle of Substitution not Connected to Practice

- Minimal staff/committee that work on substitution
- the exception: Germany Environment Agency & Swedish Chemicals Agency (>12 FTEs)

| <b>FTEs in MS authority that work on hazardous chemical substitution initiatives</b> |               |
|--|---------------|
| <b>Response</b>  | <b>(N=16)</b> |
| 0-1  | 50%           |
| 1-2  | 13%           |
| 3-5  | 25%           |
| 6-8  | 0%            |
| 9-12   | 0%            |
| More than 12   | 13%           |

### 3. Technical Feasibility Assessment in the AoA Key Challenge and Notable Support Barriers

| AoA Component   | Competent Authorities (N=10) | (Industry Representatives N=70) | (Industry Consultants N=12) |
|---|------------------------------|---------------------------------|-----------------------------|
| Identifying/screening potential alternatives for further assessment | 20%                          | 17%                             | 25%                         |
| <b>Technical feasibility assessments</b>                            | 60%                          | 44%                             | 42%                         |
| Economic feasibility assessment                                     | 10%                          | 9%                              | 17%                         |
| Hazard/risk assessment  | 10%                          | 12%                             | 0%                          |
| Decision analysis/decision support                                  | 0%                           | 4%                              | 17%                         |

- *“It takes years and significant financial and human resources to research, develop, manufacture, test and assess, support applications and uses development and to distribute new chemical products.” -Industry representative*
- *“Technical feasibility assessment requires very specific expertise on process technology that might often only be available within industry itself.... [yet] crucial for making well informed regulatory choices.” – MS representative*

# 4. The Quality and Consistency of AoAs Need Improvement

- **Scoping**
  - Limited initial screening of unacceptable alternatives (or many excluded due to overly specific performance requirements)
  - Limited transparency regarding approach and decision-rules
- **Technical Feasibility**
  - Overly prescribed technical performance requirements
  - Technical performance information availability
- **Economic Feasibility**
  - Lack of “total cost accounting”
  - Limited cost data in restriction proposals
- **Risk**
  - Lack of consistency in hazard endpoints addressed
- **Decision**
  - No transparent rules/process

## 5. Member State Programs to Support Safer Alternative Adoption Exist but are not Commonplace

- Industry sector and supply chain engagement activities
  - Strong MS recognition of challenge
  - Models of industry sector and supply chain engagement to learn from and expand
    - *“Substitution needs to be seen as stakeholder collaboration rather than something that Member States push onto industry.”*
- Inter-authority/ MS-Commission-level consultations on substitution are occurring, but not commonplace
  - Examples to learn from:
    - ECHA-coordinated Task Force on the efficiency of restrictions
      - Work focused on improving the restriction process
    - Reach Exposure Group (REEG)

## 6. Innovation Research on Safer Alternatives is not Routinely Aligned with Regulatory Priorities

“Who else needs to be involved?”

- innovation research institutes
- Research-base: Engage sustainable chemistry/technology research efforts
- Funding-base: Learn from and replicate MS innovation funding sources for substitution
  - e.g., Eco-Innovation, *Kemi Kredsløb* (Denmark)
  - e.g., Environmental Innovation Programme (Germany)
  - Technology innovation funds (remain untapped)
    - Mistra (Sweden)
    - Nesta (UK)
    - Sitra (Finland)

# Recommendations **Building Infrastructure to Support Substitution**

1. Significantly **grow ECHA and MS authority staff** capacity over time to support substitution.
  - Establish dedicated expertise/staff that can train and support others
2. Build **support for grant-mechanisms/private/public partnership funds to invest in the innovation research** (green chemistry and process-redesign) to support alternatives development for priority hazardous chemicals of concern.
  - Conduct a landscape analysis of funding/innovation agencies that could be engaged in substitution/green chemistry
3. Build **technical support infrastructure** – especially for SMEs.
  - Undertake an analysis of technical support capacities that could be engaged in substitution
4. Incorporate safer chemistry more effectively into **government procurement programs**
  - Explore development of a “safer chemical ingredient” program for specific chemical functions, such as EPA’s Safer Choice Program

# Recommendations: Engagement Capacity Building Needs

1. Institutionalize **Inter-authority collaboration/ coordination on substitution**
  - Establish interagency AoA and substitution committee that can:
    - Mentor/support smaller MS competent authorities and enhance collaboration
    - Facilitate working groups on shared challenges and concerns
2. Create mechanisms for **greater supply chain collaboration and engagement**
  - Undertake evaluation of existing supply chain collaboration models and mechanism. Establish model supply chain substitution projects including:
    - Shared performance testing evaluation
    - Demonstration sites
    - Links to innovation funds (particularly SMEs) and technical resources
3. Create **expert networks** to support authorities and industry in both assessment and adoption of substitutes preferably using already existing networks
  - Establish an on-line experts clearinghouse and other mechanisms to build community of practice



# Recommendations:

## Technical Capacity Building Needs

1. Develop more detailed guidance/guidelines/instructions for AoAs that **provide minimum components and quality criteria**
2. Develop and provide enhanced analysis of alternatives **support and training** to ECHA, including SEAC and REAC, MS authorities and industry/consultants
  - Explore feasibility of establishing a “certified AoA practitioner program”
3. Develop **web-based data resources to aide in the screening and evaluation** of alternatives by using and mining data submitted under REACH
  - Mine the REACH database

# Designing Effective Efforts to Support Innovation in Safer Chemicals

- Core Elements
  - Willingness
    - Restrictions, information requirements, planning requirements, purchasing policies, recognition
  - Capacity
    - Technical assistance, information requirements, R&D support, Education
  - Opportunity
    - Education, tax incentives, grants
- *Ashford, Nicholas. 1999. An innovation-based strategy for a sustainable environment. In Innovation-Oriented Environmental Regulation: Theoretical Approach and Empirical Analysis. Potsdam, Germany: European Commission Joint Research Centre.*

# Bottom Line

- Regulation alone is important but insufficient to drive innovation in safer chemistry. Substitution is challenging in many cases
- For reach and other regulations to support the transition to safer alternatives for substances of very high concern, the following investments are critical:
  - Greater infrastructure/capacity in government and industry
  - R&D investment connected to substitution practice
  - Enhanced collaboration within supply chains and among authorities to address substitution challenges – role for government as a facilitator
  - Improved technical resources and assistance

# Conclusions

- Thoughtful analysis of alternatives processes, combined with structures to support supply chain collaboration as well as research, innovation, and technical support can enhance the probability that successful substitution will occur.
- ECHA can support substitution moving forward by: (1) improving for conducting analyses of alternatives; and (2) providing mechanisms to support substitution activities.
- ECHA can use its regulatory authority to strengthen implementation of the REACH goal of substitution of SVHCs.
- It can also use its discretionary powers to facilitate and encourage early marketplace actions to identify, develop and adopt safer substitutes.

# Next Steps

- Work with ECHA to implement recommendations contained in the report
  - Strategic plan
  - Training and guidance materials
  - Additional research
- Engagement with agencies internationally working on substitution
- Building an international Community of Practice for alternatives assessment and substitution
  - [www.saferalternatives.org](http://www.saferalternatives.org)

# The Report

- [https://echa.europa.eu/documents/10162/13630/substitution\\_capacity\\_lcsp\\_en.pdf/2b7489e1-6d96-4f65-8467-72974b032d7b](https://echa.europa.eu/documents/10162/13630/substitution_capacity_lcsp_en.pdf/2b7489e1-6d96-4f65-8467-72974b032d7b)
- <https://newsletter.echa.europa.eu/home/-/newsletter/entry/phasing-out-dangerous-substances-how-can-we-speed-up->
- <https://www.greenbiz.com/article/us-vs-eu-chemicals-substitution-faceoff>

# Enhancing European Efforts Towards Informed Substitution: First Reactions

Webinar from Lowell Center for  
Sustainable Production  
29 November 2016

Matti Vainio  
Head of Risk Management  
Implementation Unit



## First reactions

- Report welcomed
  - Positive feedback on findings and recommendations
- Analysis of Alternatives intertwined with R&D
  - Companies are responsible for this!
  - Authorities can and should support
- ECHA is developing its strategy by mid 2017
  - A lot of experience in alternatives assessment
  - University of Massachusetts Lowell supports
  - Needs to do this in collaboration with Member States, Industry and Non-Governmental Organisations



## Some next steps

- ~200 analyses on ECHA's web
  - For [applications for authorisation](#)
  - For [restrictions](#)
- Focused workshop on alternatives to the use of hexavalent chromium in Finnish plating industry
  - Aalto University Design Factory, 25 Jan 2017
  - Organisation of R&D and funding possibilities
- Network on REACH Socio-economic analysis and Analysis of Alternatives Practitioners
  - 1/2 day session on "state of play" alternatives assessment in practice in Brussels/Antwerp May 2017

|                             |  |
|-----------------------------|--|
| Legal name of applicant(s): | <i>Sasei-Nipponen GmbH &amp; Co. KG</i>  |
| Submitted by:               | <i>Sasei-Nipponen GmbH &amp; Co. KG</i>  |
| Substance:                  | <i>Dibutyl phosphate</i>   |
| Use title:                  | <i>Use as an absorption solvent in a closed system in the manufacture of maleic anhydride (MA)</i> |
| Use number:                 | <i>1</i>   |

## More information

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# Reactions



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[Alternatives Analysis Guidance](#) to be published by the end of the year

E-List signup <http://bit.ly/scpupdates>

SCP home page <http://www.dtsc.ca.gov/SCP>

General feedback [SaferConsumerProducts@dtsc.ca.gov](mailto:SaferConsumerProducts@dtsc.ca.gov)

Contact [meredith.williams@dtsc.ca.gov](mailto:meredith.williams@dtsc.ca.gov)

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**Thank you for attending!**

