REACHLAW

COMPLIANCE. SUSTAINED.

November 16th, 2017 | Webinar

How to Prepare an Authorisation application for 2019

Some Notes

- *It is assumed that attendees have basic knowledge about REACH.*

- *Let us make this webinar interactive, please send questions*
  - *We try to answer during the webinar, if not possible, we will use email and may also include some in our Q&A on our website:*

http://www.reachlaw.fi/services/market-access-services/reach-authorisation-services/

Content

REACHLaw in a nutshell

What we do? We provide global regulatory compliance and environmental sustainability services to ensure market access and operational sustainability for global businesses

KEY FACTS ABOUT US

- ✓ Established in Helsinki
- ✓ Offices in Brussels, New Delhi and Istanbul
- ✓ 30+ toxicologists, chemists, lawyers, socio-econ. analysts, business and environmental specialists
- ✓20+ local partners in Europe, Asia, Latin-America and the USA
- ✓ 500+ REACH registrations
- ✓ Language support in 10+ different languages
- ✓ more info about Us: www.reachlaw.fi

SERVICE AREAS

✓ Global chemicals regulatory compliance, e.g.

REACH	CLP
Biocides	China REACH
TCCA-Korea	Turkey

✓ We prepare the required dossiers to authorities, SDSs, labels and provide related business strategy, legal and monitoring support.

✓ www.compliantsuppliers.com

OUR CLIENTS

✓ More than 350 customers from 40+ countries, from Fortune 100 companies to SMEs.

✓Major industries served: Oil, chemicals, specialty chemicals, metals, space sector and other downstream users (DU) industries

✓ Our customers are manufacturers, importers, traders, DU´s, industry associations and governmental organizations.

REACHLaw's Authorisation Experiences

Substance	Type	Industry Sector
Triton X 100	Upstream	In Vitro Diagnostics
Diarsenic trioxide	Single DU	Mining
Diarsenic trioxide	Single DU	Mining
Sodium dichromate	Multi-site DU	Mining
Sodium chromate	Group DU	Professional and Consumer electrical products
Chromium trioxide	Group DU	Multiple
Chromium trioxide	Single DU	Professional and Consumer products
Sodium chromate	Upstream	Textiles
Chromium trioxide	Single DU	Aerospace and Defence
Chromium trioxide	Sector Specific	Aerospace and Defence
2,2'-dichloro-4,4'-methylenedianiline	Upstream	Polyurethane
Chromium trioxide	Upstream	Multiple

Entry Nr	Substance	Intrinsic property(ies) referred to in Article 57	Latest application date	Sunset date
32	1-Bromopropane (n-propyl bromide) EC No: 203-445-0 CAS No: 106-94-5	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020
33	Diisopentylphthalate EC No: 210-088-4 CAS No: 605-50-5	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020
34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7 rich EC No: 276-158-1 CAS No: 71888-89-6	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020
35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters EC No: 271-084-6 CAS No: 68515-42-4	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020
36	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear EC No: 284-032-2 CAS No: 84777-06-0	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020
37	Bis(2-methoxyethyl) phthalate EC No: 204-212-6 CAS No: 117-82-8	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020

Entry Nr	Substance	Intrinsic property(ies) referred to in Article 57	Latest application date	Sunset date
38	Dipentylphthalate EC No: 205-017-9 CAS No: 131-18-0	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020
39	N-pentyl-isopentylphthalate EC No: — CAS No: 776297-69-9	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020
40	Anthracene oil EC No: 292-602-7 CAS No: 90640-80-5	Carcinogenic (category 1B, PBT, vPvB	4 April 2019	4 October 2020
41	Pitch, coal tar, high temp. EC No: 266-028-2 CAS No: 65996-93-2	Carcinogenic (category 1B, PBT, vPvB	4 April 2019	4 October 2020
42	4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (covering well-defined substances and UVCB substances, polymers and homologues) EC No: — CAS No: —	Endocrine disrupting properties (Article 57(f) — environment)	4 July 2019	4 January 2021
43	4-Nonylphenol, branched and linear, ethoxylated (substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof) EC No: — CAS No: —	Endocrine disrupting properties (Article 57(f) — environment)	4 July 2019	4 January 2021

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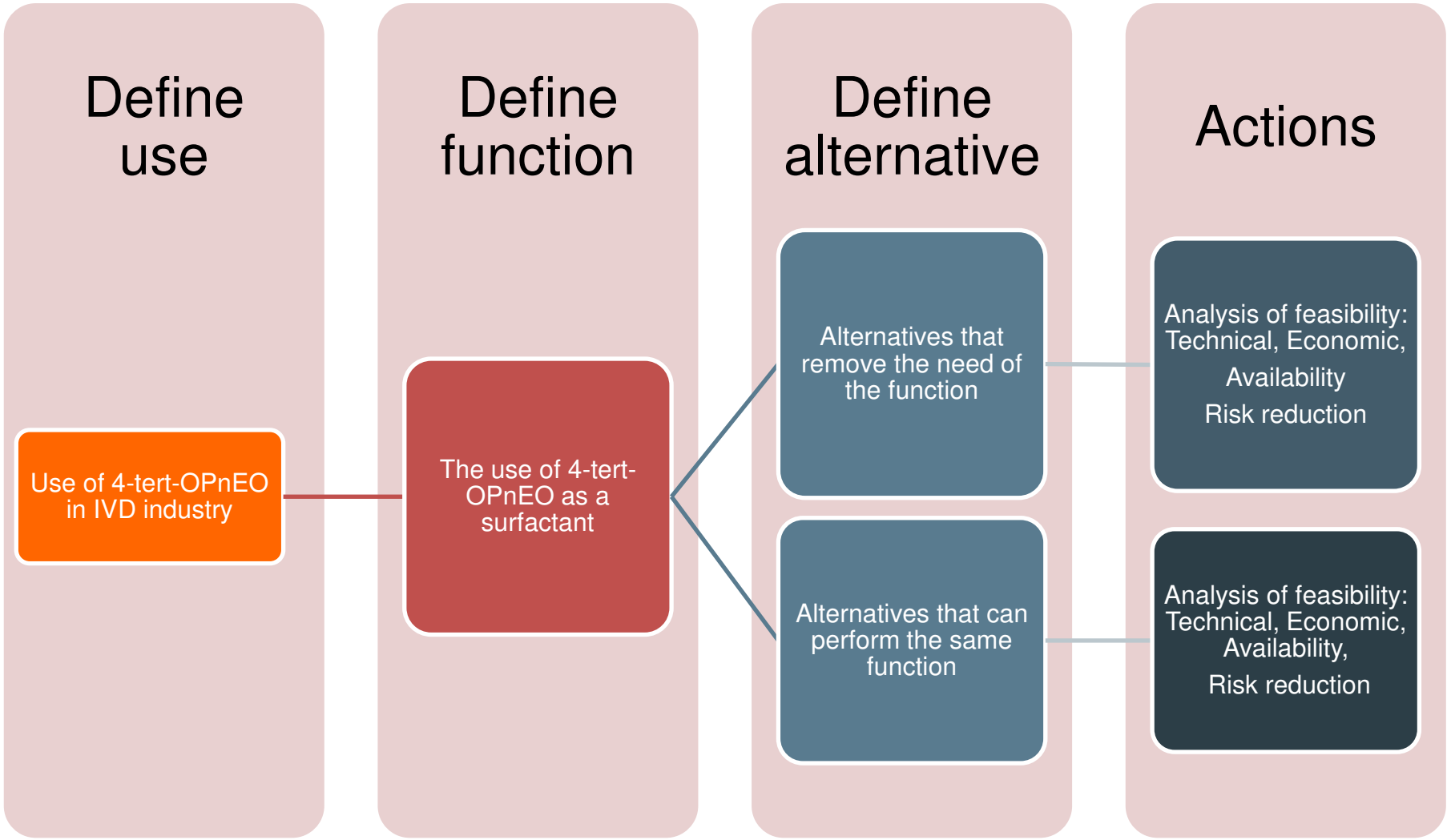
Analysis of Alternatives

Socio-Economic Analysis

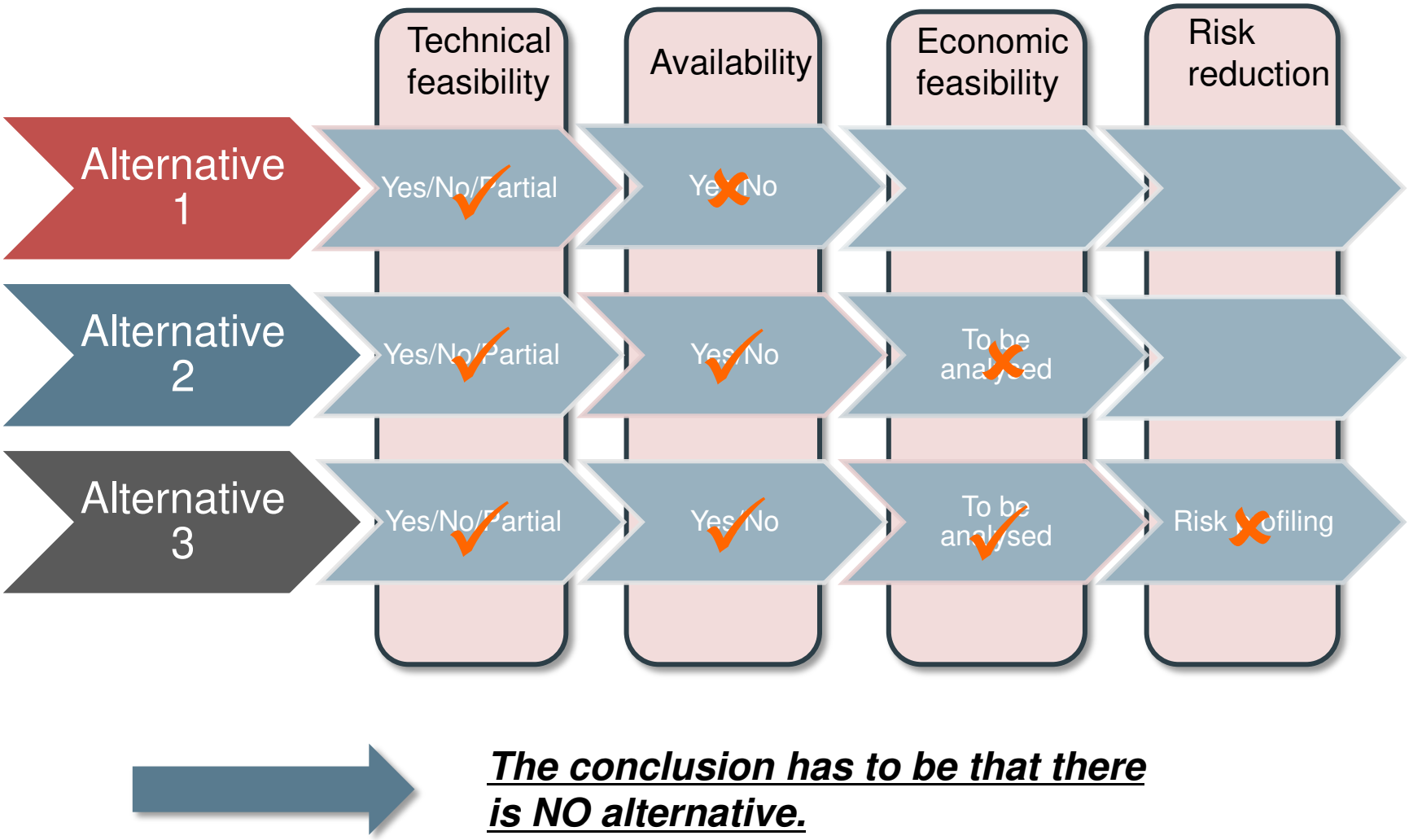
Chemical Safety Report

Application Strategy with past REACHLaw examples

Analysis of Alternatives



General Approach to the Analysis of Alternatives



The conclusion has to be that there is NO alternative.

Analysis of Alternatives

- Are there differences with the approach for PBTs, vPvB, etc.
  - Not really!

    - The AoA should still:
      - Define alternatives
      - Explain reasoning behind continued use e.g. standards, etc.
      - Elaborate on R&D and feasibility of alternatives
        - Technical feasibility
        - Economic feasibility
      - Explain any actions required & time-lines to change
      - Assess the availability

Analysis of Alternatives

- If you have already identified an alternative?
  - Possible to implement before the Sunset Date?
    - No Authorisation required
  - Possible to substitute in part by the Sunset Date?
    - Authorisation required for that part/tonnage where substitution is not possible
    - Remaining tonnage should be substituted
    - Substitution Plan required
  - Not possible to implement alternative in any way before the Sunset Date?
    - Authorisation required for the full tonnage
    - Substitution Plan required

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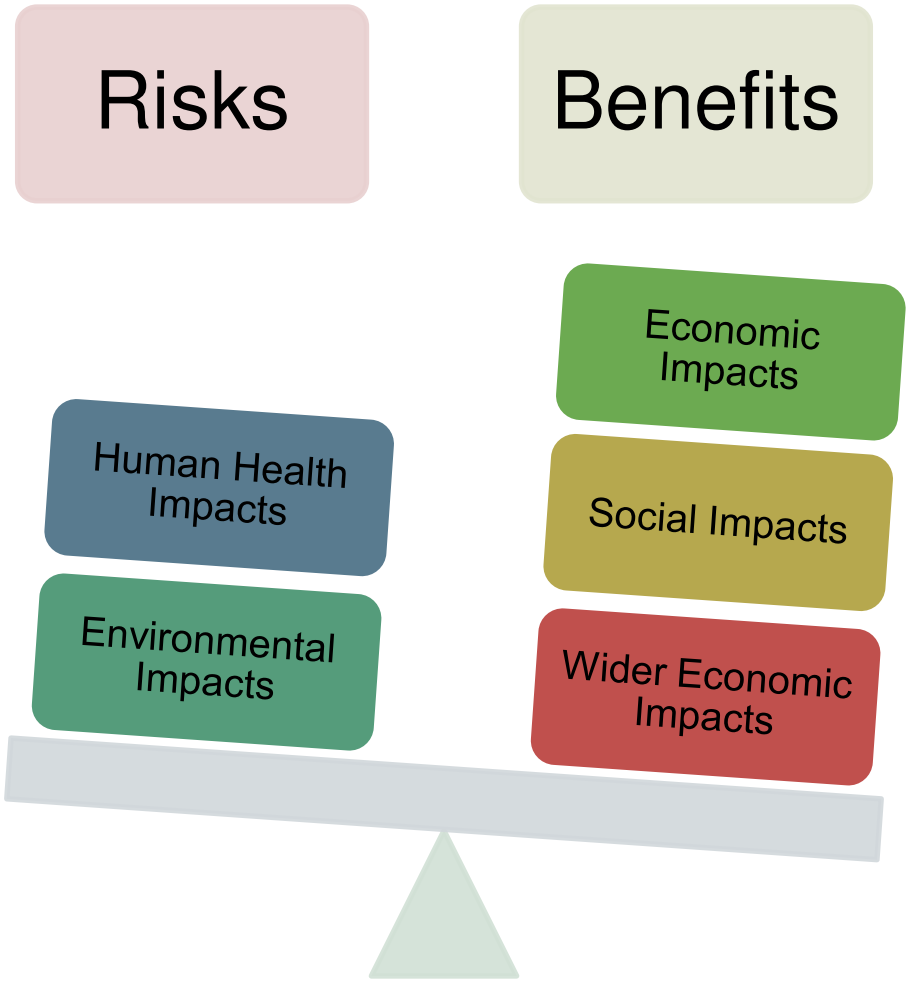
Socio-economic analysis (SEA)



SEA process and information needs

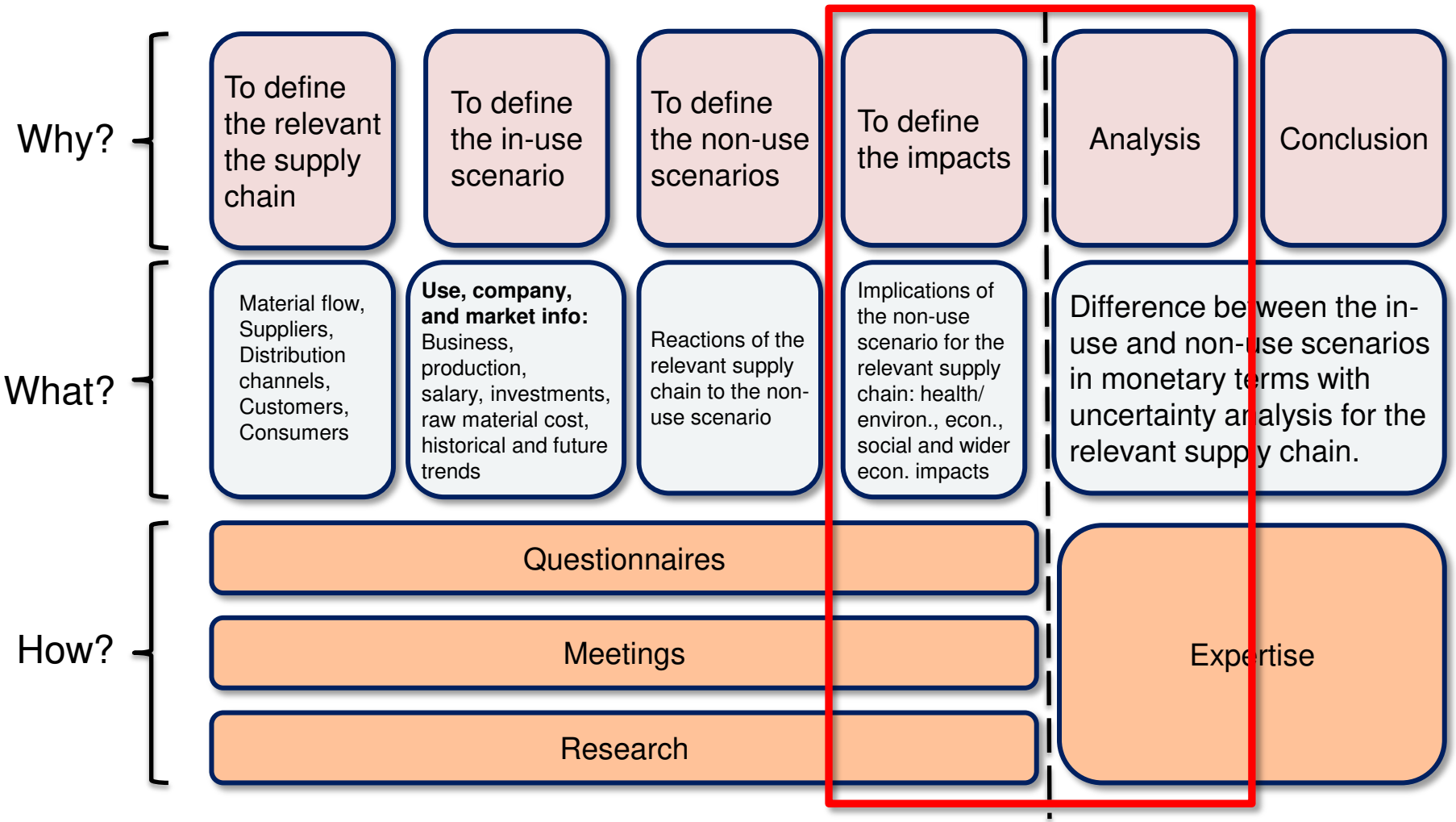
Impacts:
- Human health/ environment
- Economic
- Social
- Wider economic

Why?	To define the relevant the supply chain	To define the in-use scenario	To define the non-use scenarios	To define the impacts	Analysis	Conclusion
What?	Material flow, Suppliers, Distribution channels, Customers, Consumers	**Use, company, and market info:** Business, production, salary, investments, raw material cost, historical and future trends	Reactions of the relevant supply chain to the non-use scenario	Implications of the non-use scenario for the relevant supply chain: health/ environ., econ., social and wider econ. impacts	Difference between the in-use and non-use scenarios in monetary terms with uncertainty analysis for the relevant supply chain.	
How?	Questionnaires				Expertise	
	Meetings					
	Research					

SEA process and information needs

What changes?

Impacts:
- **Human health/ environment**
- Economic
- Social
- Wider economic



Defining impacts – Human health & Environmental

- Before
  - Quantitative estimates of the relationship between individual exposure and the incidence of a defined health effect,
  - Assessment of exposure,
  - A measure of actual impact of the health effect,
  - An estimate of the total population exposed,
  - Monetisation of CMR-substance's exposure via willingness-to-pay estimate.
- After
  - Quantification of impacts is not currently possible for most PBT/vPvB substances, which makes the evaluation whether the socio-economic benefits of use of the substance outweigh the risks for an application for authorisation challenging.

ECHA's proposition: Cost-effectiveness analysis

- ECHA (SEAC) has tried to develop a benchmark assessment method
  - Cost-effectiveness analysis (CEA) based on emissions reduction of PBT or vPvB substance and the compliance costs

- The cost of a certain (policy) measure is related to some non-monetary parameter, for instance the amount of emission reduction that can be achieved with this measure

- To conclude on the proportionality of policy measures based upon a cost-effectiveness assessment, there is a need for a benchmark
  - the decision maker wants to know if a specific level of cost should be considered as proportional or disproportional.

Cost-effectiveness analysis in practice

1. step: **Kilograms of avoided substance use** OR **Kilograms of avoided emission (or exposure reduction)**

2. step:
- **Substitution cost**
- **Replacement cost**
- **Remediation cost**

3. step: **Cost per avoided substance use (EUR/kg)** OR **Cost per avoided emission (EUR/kg)**

4. step: **Compare to a benchmark to conclude proportionality**

Endocrine disruptors

- ECHA is preparing Q&As for future applicants of endocrine disruptors (EDs) for the environment

- These Q&As will clarify what could be the approach for
  - the risk assessment (RAC-related issues)
  - the impact assessment (SEAC-related issues)

- ECHA expects to make these Q&As public by the end of 2017 / beginning of 2018

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CSR

- Authorisation CSR expected to be more detailed than Registration CSR
  - Contains greater detail on the Annex XIV property(ies)
  - Site specific exposure scenario
  - Different factors to consider for exposure

- Reflect relevant and realistic information on applied for uses
- Needs to provide ECHA with:
  - Clear understanding of the process
    - Use(s) clearly described
    - Use(s) conducted at several sites…own sites?
    - Other use(s) along (up/down) the supply chain in other companies, where applicable?

Factors to consider with the CSR

- Main focus on risk to workers:
  - Biomonitoring?
    - When?
  - Technical controls?
    - What and Where?
  - Operational controls?
    - Who, What and Where?
  - Personal controls?
    - Who and When?

- How does what you are doing now correspond to what is expected from other national laws, Regulations or directives?

Factors to consider with the CSR - EDs, etc.

- Is there a safe level?
  - Yes, No, Maybe?

- Environmental emissions monitoring?
  - Technical controls?
    - What and Where?
  - Operational controls?
    - Who, What and Where?

- How does what you are doing now correspond to what is expected from other national laws, regulations or directives?
  - Water Framework Directive?

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What else should be considered?

- Type of application:
  - Upstream covering all Downstream uses
  - Upstream covering specific Downstream uses
  - Individual Downstream
  - Group Downstream
- Timing
- Scope
- Are some uses exempt?

The Aim of ALL AfAs is to reduce the uncertainty around using an SVHC

Examples of different types of AfA prepared by RL

Substance	Type	Industry Sector
Triton X 100	Upstream	In Vitro Diagnostics
Diarsenic trioxide	Single DU	Mining
Diarsenic trioxide	Single DU	Mining
Sodium dichromate	Multi-site DU	Mining
Sodium chromate	Group DU	Professional and Consumer electrical products
Chromium trioxide	Group DU	Multiple
Chromium trioxide	Single DU	Professional and Consumer products
Sodium chromate	Upstream	Textiles
Chromium trioxide	Single DU	Aerospace and Defence
Chromium trioxide	Sector Specific	Aerospace and Defence
2,2'-dichloro-4,4'-methylenedianiline	Upstream	Polyurethane
Chromium trioxide	Upstream	Multiple

Upstream covering all Downstream uses

- Only Representative of a client outside of the EU
- DUs all SME
- About 100 companies within the supply chain
  - Difficulties in contacting all the DU companies
  - Developing surveys to ensure that the right information is given
  - Define grouping/classification of companies within the supply chain can be difficult
  - What is enough in terms of representativeness?

These types of application take a long time to develop and prepare

Upstream covering specific Downstream uses (Sector Specific)

- Space Task Force
  - Space sector is a niche sector
  - Part of the larger Aerospace industry
  - Similarity in process, exposure, alternative suitability, non-use scenario and socio-economic impacts.
  - Smaller, more manageable information collection
    - Fewer companies in the supply chain
    - More visibility
  - Potential for missing links in the supply chain
  - Business model of sub-contractors

Individual Downstream

- Mineral Processing company
  - Intermediate use exemption?
    - ECHA disagree
    - Options:
      - Appeal and not apply for Authorisation
      - Appeal and apply
  - Authorisation as an Risk Management Measure
    - Provides a level of business certainty
    - Protects uninterrupted use (if application made before LAD and decision is after SD…)

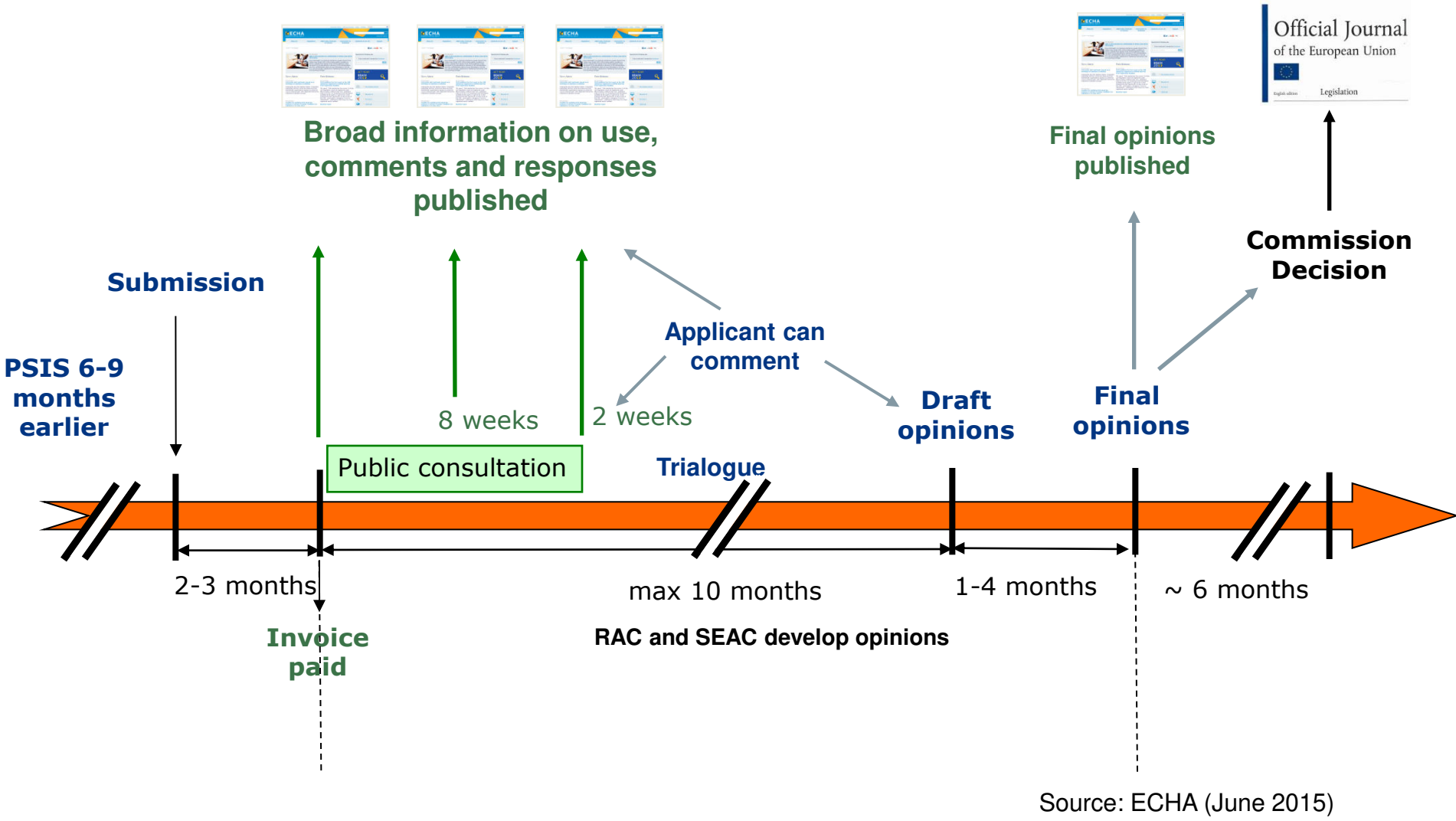
Group Downstream

- Group of “Job Shop” micro sized companies
  - Hard chrome plating for a variety of industries
  - Customer specified processes and standards
  - Unable to substitute as customer specific requirements
  - Too small to influence larger downstream sectors

- Micro companies unable to introduce multiple process lines
  - Cost
  - Physical space
- Identify commonalities
  - Exposure
  - Alternatives
  - Non-use scenario

After Submission

Decision making: ECHA process



Source: ECHA (June 2015)

Conclusions

Conclusions

- Deciding what application strategy suits your company is key
  - Need to evaluate the likelihood of success
    - Previous experience is critical in deciding/evaluating this.
- The inclusion of substances with environmental hazard endpoints introduces additional difficulty
  - Socio-economic analysis
  - Chemical Safety Report
- Authorisation can be used as a Risk Management Measure
  - Provides a level of business certainty
  - Can be used when unclear exemption, etc.

Contact Us:

If you are interested in applying for Authorisation and would like to discuss this with us, please feel free to contact us: sales@reachlaw.fi

Also, please visit the Authorisation section of our website and our Q&A section: http://www.reachlaw.fi/services/market-access-services/reach-authorisation-services/


Thank
You
Asante
Shukria
Dhanyavadagalu
Maake
Kiitos
Vinaka
köszönöm
Dankscheen
спасибо
Kam Sah Hammida
Manana
Dankon
Matondo
Terima Kasih
Taiku
Tack
Diolch i Chi
Biyan
Mauruuru
Dank Je
Blagodaram
Ngiyabonga
Dziekuje
Chokrane
Arigato
Grazie
Juspaxar
Gracias
Mochchakkeram
Tingki
Paldies
Gratias Tibi
Obrigado
Khap
Khun
Kop
Kia Ora
Djiere Dieuf
Eskerrik Asko
Najis Tuke
Go Raibh Maith Agat
ขอขอบคุณคุณ
Salamat
Merci
Di Ou Mèsi
Welalin
Danke
Grazas
Nirringrazzjak
Hvala
Bedankt
Dakujem
Děkuji
Suksama
Ua Tsaug Rau Koj
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