



REACHLAW
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Joint downstream users' application

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.

Content


Why and how

Data representativeness

Confidentiality

Lessons learned

Why make a joint downstream users' application?



Joint DU Afa to fill the gap

Single DU Afa

- + Specific
- + Data complete
- Costly
- Certainty

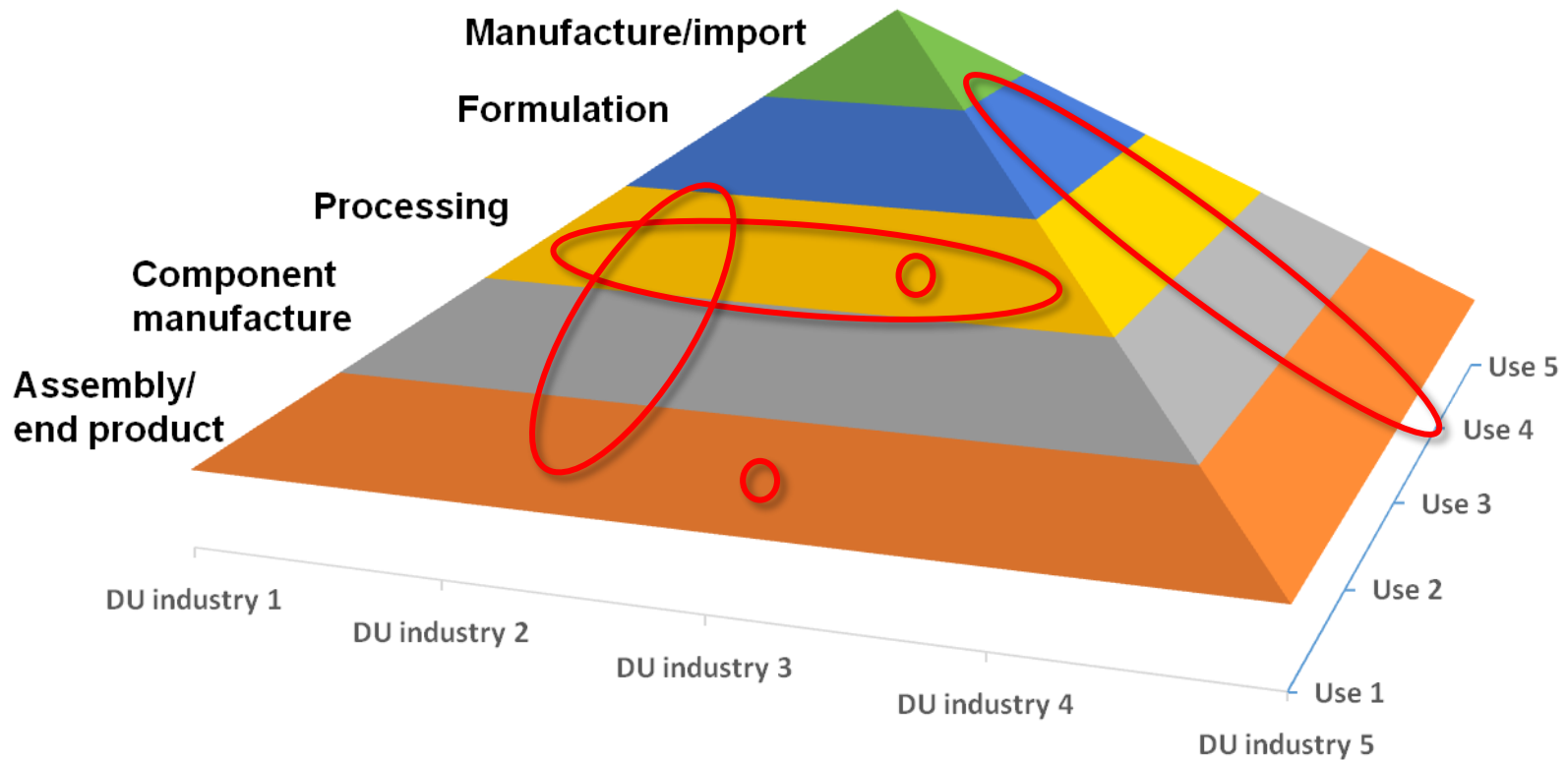
Broad use upstream Afa

- + Cost effective
- Heterogeneity
- Data incomplete
- Uncertainty

Why make a joint downstream users' application?

- The formation of consortia often makes sense for the purposes of:
 - cost sharing;
 - pooling knowledge/data and;
 - presenting a unified industry voice
- However, to prepare a strong application, it is important that a homogeneous and manageable group is formed:
 - connected by the common desire to obtain authorisation;
 - That shares similar uses, substitution and/or validation requirements and;
 - With similar socio-economic situations.

Different ways to get organized



Example 1. CRAN - finding a homogeneous group

CrO₃ used in hard chrome plating:

Questions designed to analyse the similarities/differences according to the **authorisation** requirements

Analysis

Role in supply chain

Potential Exposure, workers

Potential Exposure, environment

Alternatives
Technical
Economic
Risk level

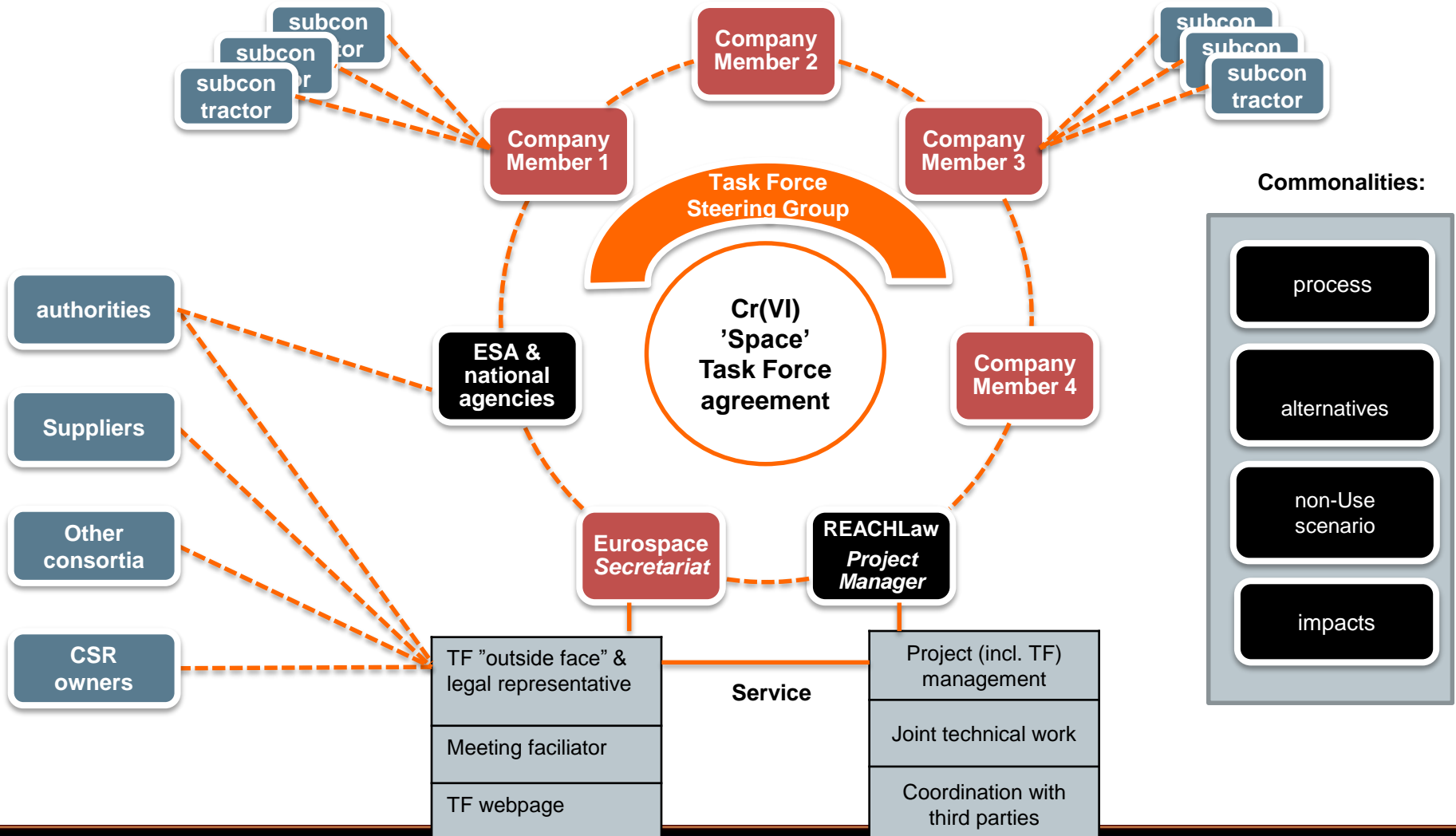
Non-use scenario

Outcome: One or several groups

CRAN - find a homogeneous group and simple consortium organization

	Size	Business model /role in supply chain	Process type	Non-use scenario
Company 1	Small	Service company	Manual	Closure
Company 2	Small	Service company	Manual	Closure
Company 3	Small	Service company	Manual	Closure
Company 4	Small	Service company	Manual	Closure
Company 5	Small	Service company	Automatic	Closure
Company 6	Medium	In-house plating	Automatic	Sourcing from outside of EU
Company 7	Medium	In-house plating	Manual	Sourcing from outside of EU

Example 2. Space Task Force¹ for CrVI authorisation - common DU industry specificity



Example 3. Joint DU Afa filed by an upstream player

- Applicant as the distributor (repackaging use) to cover
- 11 downstream users with the common technology (OC & RMM) concerning the use of CrVI substance
- Unlike broad use definition upstream application, this kind of application covers DUs that are limited in number and most/all are identifiable who can also provide data.

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Data representativeness

CSR

- Data completeness vs. Data representativeness
- Data completeness
 - All types of data that complement each other (biomonitoring, personal sampling, static sampling, environment emission)
 - Contextual information - relevance
- Data representativeness
 - Justification
- Most wanted: complete data set on one/some sites + good justification for representativeness of the rest
- Less wanted: incomplete data set on some sites but complement/reinforce each other + good justification for representativeness
- Unwanted: incomplete data set and lack justification for representativeness

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Confidentiality

- The use of trustee is inevitable
- Being transparent is the best way the applicant(s) can help themselves
 - Reducing uncertainty
- Most sensitive issues:
 - potential alternatives and test results related to them.
 - DUs with different views on the alternatives are not advised to apply jointly.
 - Profit & loss information
 - Remedies: use of industrial average, supply the profit information only when absolutely necessary

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Lessons learned

- Authorisation is about the uses, and downstream users need to play a central role.
- There are different ways to get organized jointly and finding homogeneity in some or all aspects is the key
 - It is not advised to jointly apply if no common view on the alternatives can be formed;
 - The joint applicants need to share homogeneity on all of some of the following aspects:
 - Same view on the substitution prospect
 - Risk level (process, OC and RMM)
 - Non-Use scenario
- Applicants should be able to present complete data set, or at least able to prove the data representativeness.

Contact details

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