

Strategic and Legal Considerations for Organization of REACH Authorization

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Summary

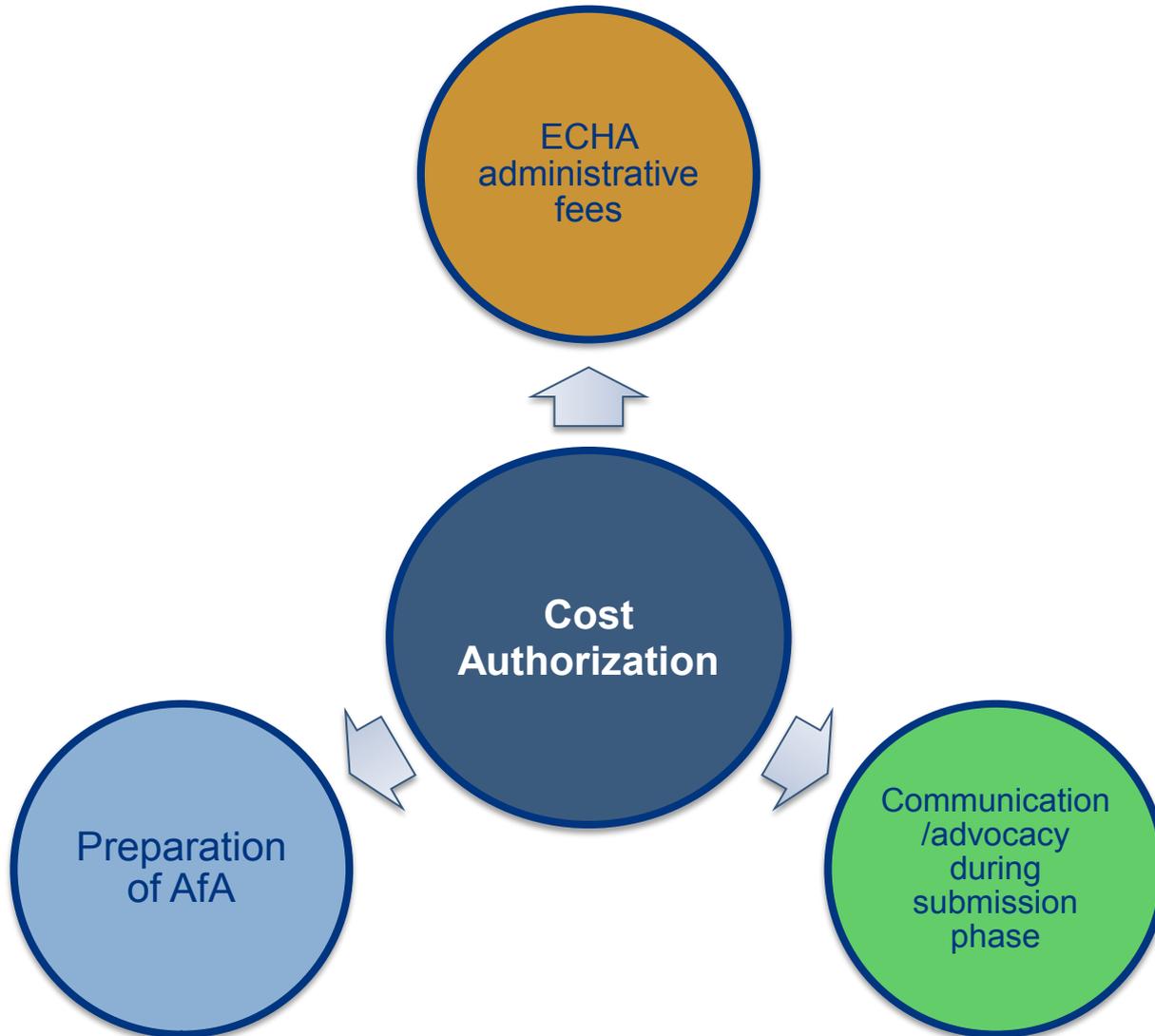
Strategic and Legal Considerations

- Cost of authorization
- Impact of the company's authorization status on its future position in the market
- Pros and cons of cooperating with other companies
- Consortia yes or no, lessons learned
- Competition law concerns

Acronyms Used

AfA	Application for Authorization
AoA	Analysis of Alternatives
CBI	Commercially sensitive and therefore, Confidential Business Information
DU	Downstream User
LAD	Latest Application Date (<i>set in Annex XIV REACH</i>)
RAC	ECHA - Risk Assessment Committee (<i>national experts</i>)
SEA	Socio-Economic Analysis
SEAC	ECHA - Socio-Economic Analysis Committee (<i>national experts</i>)
TFEU	Treaty on the Functioning of the European Union

Cost of Authorization



Cost of Authorization - Cost reduction options

ECHA Administrative Fees

- Upstream authorization
- Reduce number of legal entities filing AfA in a group of companies
- Reduce number of uses applied for
- Joint application

Example for joint application:
- 1 large company, five uses = ECHA fees per company EUR 95.940.
- If filed jointly (5 companies): EUR 51.160

Preparation of AfA

- Share cost of preparation with other companies in a Consortium at least for CSR and AoA

Communication during submission phase

- Joint application or agreement to file on the same date to achieve same public consultation period and alignment of RAC/SEAC questions

Cost of Authorization - Pitfalls of cooperation from a cost point of view

- Different levels of activity of the cooperation partners, confidentiality issues, and different data sets (e.g. exposure data) may be difficult to manage and actually increase the cost. Cooperation is a cost item in itself
- Unless the parameters of cooperation are fixed in advance, cost savings may not be realized in the end (e.g. cooperation partners may discover over time that they are better off applying for their individual authorization rather than relying on an upstream application; e.g. alternatives are discovered during the preparation phase or companies change their business model and former cooperation partners back off).



Impact of a Company's Authorization Status on its Market Position

- There is considerable input from third parties including NGOs and competitors, not only on the AoA but also on the SEA before an authorization is granted. Hence, authorization has a market value per se
- If a company relies on an upstream authorization, its market position will be weaker, as it is dependent on its suppliers, who may disappear
- Suppliers constantly restructure their product portfolios and will urge their customers to purchase alternative (more expensive?) candidates
- Having a REACH authorization is a license to operate and a value in case of M&A
- The longer the review period the better the market position and planning certainty.

Pros and cons of cooperating with other companies



A) Pros

- Cost savings (but see above)
- Increased knowledge base (AoA, exposure data)
- Harmonized position on AoA (review period)
- Increased opportunities for upstream application (if many DUs ask, the suppliers may not refuse) and thereby increased supply chain security (for many SMEs, obtaining individual authorization is too difficult (lack of manpower and knowledge) and too costly).

Pros and cons of cooperating with other companies *(cont'd)*

B) Cons



- Cost risks
- Timing issues (coordination requires time)
- Risk of reduced length of review period because cooperation partners may not share commercially sensitive data on alternatives, R&D or socio-economic impacts
- Harmonization of exposure information or modeling may be worst case or lowest common denominator thereby reducing success rate of AfA or length of review period
- Constant risk to divulge company strategies to competitors.

Consortia yes or no, lessons learned

A) YES

- The “raison d'être” of consortia is the collection of information which would otherwise be difficult to collect, the possibility to harmonize the approach for authorization (definition of uses, availability of alternatives), the potential to facilitate an upstream application, and hopefully some cost savings
- Consortia are the only valid option for cooperation. Cooperation within trade associations will not allow for inclusion of upstream or downstream parts of the distribution chain
- Consortia in which DUs do not participate may have difficulties to collect AoA and SEA data
- For SMEs, participation in consortia or relying on an upstream supplier may be the only viable way to be able to continue using Annex XIV substances.

Consortia yes or no, lessons learned *(cont'd)*

B) NO

- Establishing a consortium with the fiercest competitors makes no sense as they will not commit to cooperate and share information, unless they have common suppliers or DUs
- There must be a commonality of uses in the Consortium
- Special uses do not lend themselves to being included in a Consortium.

Consortia yes or no, lessons learned *(cont'd)*

C) Lessons learned

- Consortia must be established approximately two years before the LAD as the organization and data collection takes time. Last minute consortia are not a route to success
- The more complicated the Consortium (several substances, several uses) the higher the cost
- Large consortia have specific dynamics and will require strong leadership to succeed
- DU consortia are not helpful as they lack the possibility to pursue upstream applications and will not lead to substantial cost savings
- Do not underestimate industry dynamics. The interests of consortia members change over the lifetime of a Consortium (bankruptcies, M&A, divestitures, R&D).



Consortia yes or no, lessons learned *(cont'd)*

- It seems impossible to set up a Consortium that would represent an entire industrial sector. Hence a complete harmonization of approaches is not possible
- There are very few authorization consortia yet (... and there are few AfAs) (uses different?, business secrets?, ability to replace?, relocation?, intermediate status?)
- A considerable amount of consortium management time is spent on third party communication (inquiries from DUs, other users).

Competition Law Concerns - General

Information exchanges

- Article 101 TFEU: includes exchange of certain “commercially sensitive” information between competitors
- In the past, information exchange was considered as a means of enforcing a broader anticompetitive agreement restrictive of competition by object
- Now, pure information exchange may be recognized as a potentially serious antitrust offense
- “Commercially sensitive” information in competition law:
 - Traditionally: price, market share, costs, capacities, investments
 - Horizontal Guidelines: “strategically useful” information (§ 107)
- Potentially in REACH: AoA (economic and technical feasibility of alternatives) and SEA.



Competition Law Concerns - General

John Deere Case- Information exchange is restrictive by effect

- Case C-7/95, John Deere (known as “UK Tractor”, 1998)
- Basic principle: each economic operator must determine its conduct freely. Information uncertainty is part of the normal competitive process
- Reduction or removal of uncertainty is anti-competitive insofar as it has the EFFECT of restricting competition:

§ 90: “In view of that reasoning, the Court of First Instance must be considered to have concluded correctly that the information exchange system reduces or removes the degree of uncertainty as to the operation of the market and that the system is therefore liable to have an adverse influence on competition between manufacturers.. ”

Competition Law Concerns - General

T-Mobile Netherlands- Information exchange is restrictive by object

- Case C-8/08, T-Mobile Netherlands BV, 2009
- Case involving only one meeting between mobile operators in The Netherlands
- No relationship to the retail market, but exchange on conditions applied to dealers with regard to new subscriptions
- Restriction by object

§31: “In order for a concerted practice to be regarded as having an anti-competitive object, it is sufficient that it has the potential to have a negative impact on competition. In other words, the concerted practice must simply be capable in an individual case, having regard to the specific legal and economic context, of resulting in the prevention, restriction or distortion of competition within the common market.”

- No requirement of impact on consumer prices

§39: “in order to find that a concerted practice has an anti-competitive object, there does not need to be a direct link between that practice and consumer prices.”



Competition Law Concerns - General

Banana Case

- Case T-587, Fresh Del Monte Produce, Inc., 2013 – under appeal
- Exchange of weekly quotation prices prior to setting actual prices
- Commission decided that parties *“cannot have failed to take into account the information received”*
- *“Pre-pricing communications”* are restricted by object
- Key market particularities: quota system setting maximum ceiling for banana imports into the Community (taken into account for the purpose of calculating the level of the fine) and the highly perishable nature of the product.

Competition Law Concerns - General

The Guidelines refine the concept of “information exchange”

- Restrictions by object: information exchange between competitors of individualized data regarding intended future prices or quantities (§ 74)
- Cartels: private exchanges between competitors of individualized data regarding intended future prices or quantities because “*they generally have the object of fixing prices or quantities*” (§ 74)
- Restrictions by effect: other forms of exchange of sensitive information “*likely to have an appreciable adverse impact on one or several of the parameters of competition such as price, output, product quality, product variety or innovation*” (§ 75) (emphasis added)
- When information exchange scheme is part of a broader arrangement, it is treated as ancillary to the main arrangement.

Competition Law Concerns - REACH

Information exchange among companies for the purpose of the REACH AfA

- Every document submitted to ECHA, with the exception of the Confidential Annexes, will become publicly available
 - Certain information will be published in the public consultation
 - Information is already available from ECHA dissemination website
 - Competitors may obtain information through access to information requests
- Applicants submitting a joint AfA have access to all the information contained in the AfA
- According to Article 118(2) REACH, certain information is considered *a priori* CBI.

Competition Law Concerns - REACH

Information exchange among companies for the purpose of the REACH AfA - in practice

- CBI identified by the Applicant in the first AfA
 - in the AoA, the substance function, i.e.
 - details of the tasks performed by the substance, critical properties and quality criteria providing key process parameters and function conditions
 - factors affecting the suitability of alternatives
 - the economic feasibility of the alternatives
- CBI identified by the Applicant in the second AfA
 - information on the environmental impacts
 - economic feasibility analysis for: price of the substance, cost for plant conversion, cost for a new license
 - details of Applicant's historical, ongoing and planned R&D.

Competition Law Concerns - REACH

The two jointly submitted AfAs apply confidentiality criteria in different ways

- In the first case, the AfA was accompanied by two separate Confidential Annexes: one Confidential Annex common to all applicants, and one Confidential Annex containing specific data prepared by the “*lead applicant*”
 - Such solution is misleading, and it is not always clear what type of information is included in the Confidential Annex
- In the second case, it is argued that permission was not granted for the applicants to set out full details in the application (i.e. the R&D program), not even in the Confidential Annexes
 - It remains to be seen how this will impact the third party comments and RAC/SEAC opinions.

Competition Law Concerns - REACH

Competition law risks resulting from an exchange of confidential information between competitors

- If (1) the market is fragmented, (2) the exchanged information consists of aggregate data and weighted averages, and (3) consumers/suppliers share in the advantages offered by such exchanges – NO concern
- In (1) concentrated markets, if (2) the information exchange were to result in increased transparency of market conditions and costs, allowing competitors to align prices to weighted costs, price competition among them would be diminished or eliminated – CONCERN
 - Commission or national competition authority - burden of proving the materiality of anticompetitive effects
 - The information exchange practice may still be eligible for an individual exemption pursuant to Article 101(3) TFEU
- The chemical industry is in most cases (1) highly concentrated, (2) with few suppliers and (3) a highly dispersed group of downstream users. As the market is typically supply driven, every exchange of information must be treated with careful attention.



Competition Law Concerns - REACH

Principles that must be observed in Consortia work

- The technical feasibility in the AoA generally is 'genuinely public information'
- Exchanging detailed information about alternatives is of concern regarding whether, when, and how companies switch to an alternative ----> must be considered as CBI
- The exchange of CBI is OK via a third independent party
- In case of a full joint application, the applicants would need to:
 - (1) work through a third party (consultant)
 - (2) be restricted in their access to their own application in the REACH-IT and
 - (3) the follow-up communication between ECHA and joint applicants to be channeled exclusively via the consultant
- **In case of doubt**, information listed in the AfA should be classified as CBI, even if this is contrary to the transparency sought in public consultation.

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