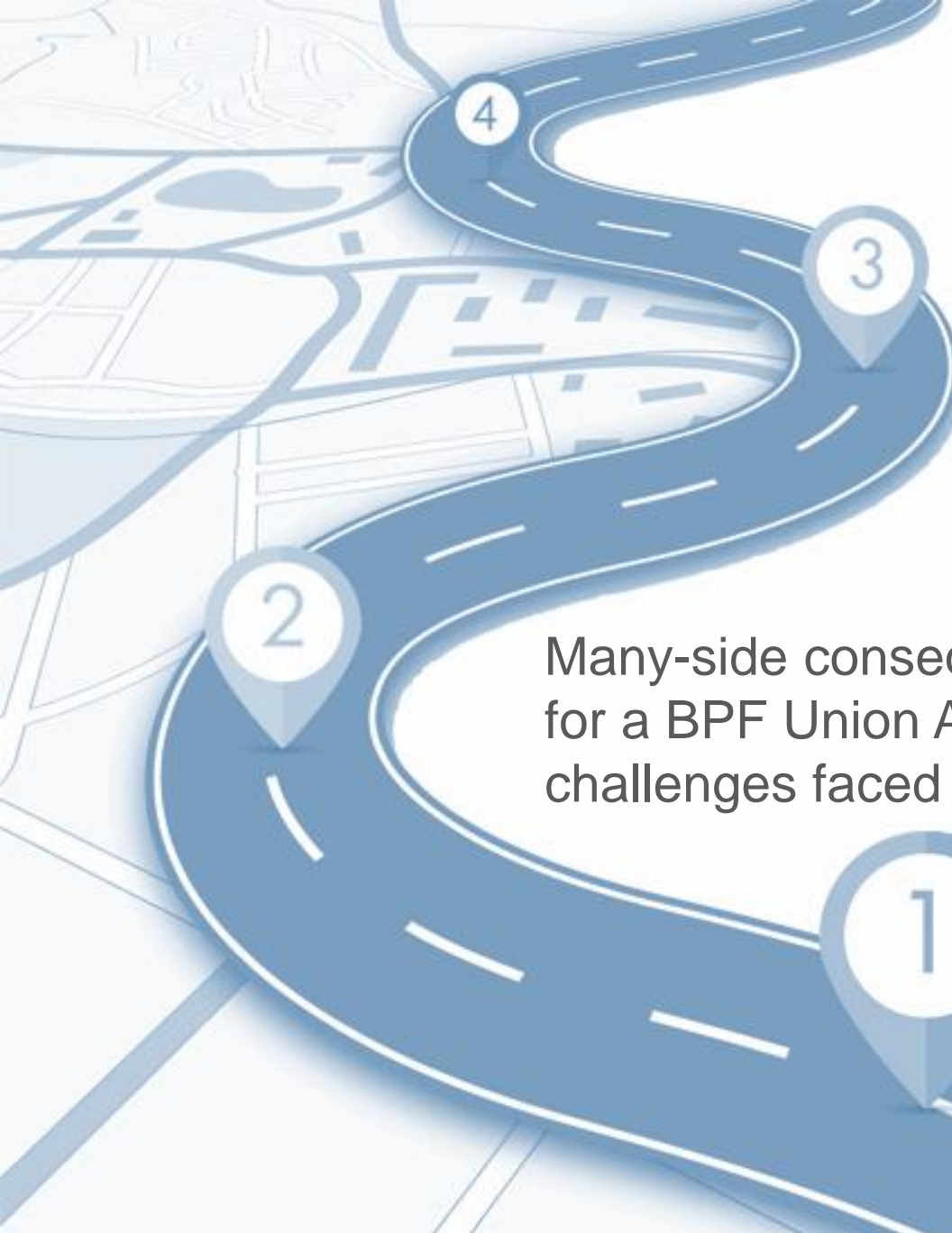




**Worldwide  
services**

We provide excellence in hygiene  
& water treatment for a sustainable world.



Many-side consequences of the decision to go for a BPF Union Authorisation: multiple challenges faced during the process.

## AGENDA:

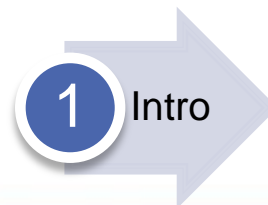
- Introduction
- Upstream decision taking
- Downstream decision taking
- Most critical issues encountered
- Challenges for the future

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# Introduction

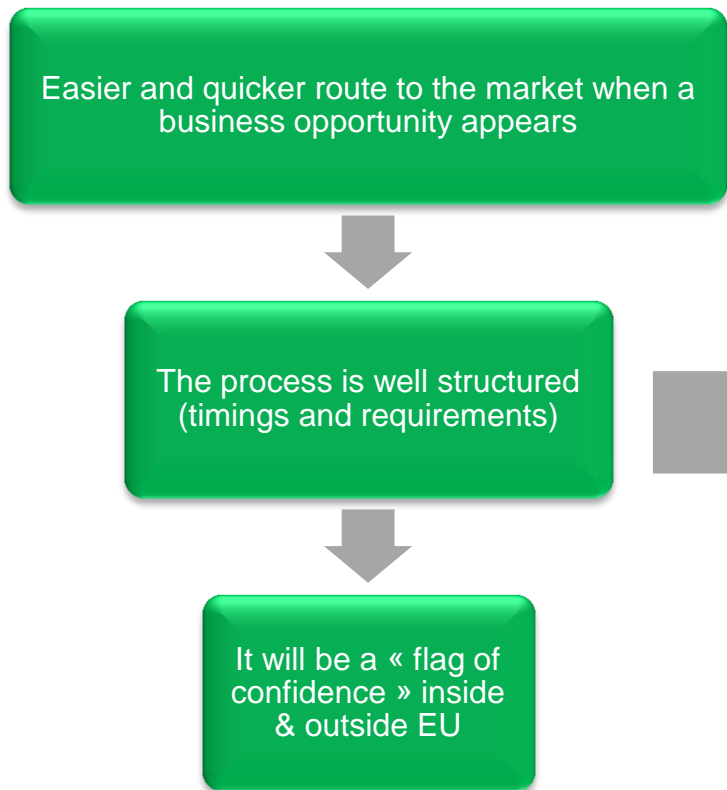
- Union authorisation: goal and conditions are well defined but new experience.
- What “considerations” upstream and downstream a decision to go for the UA should be taken into account for an SME?



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# Upstream stage gates

## General benefits of UA



## Strategic gates



## Challenges within company



- Introduction
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- **Downstream decision taking**
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# Downstream Stage Gates

## Downstream Process

-  Review of the R&D program
-  Reshape the regulatory resources
-  Evaluate which national authority is the most appropriate
-  Choose the right partner consultant « pioneering project »
-  Integrate your customer's expectations now !
-  Integrate link with active substance and dataholder of info of A.I.
-  Review of the route to market process

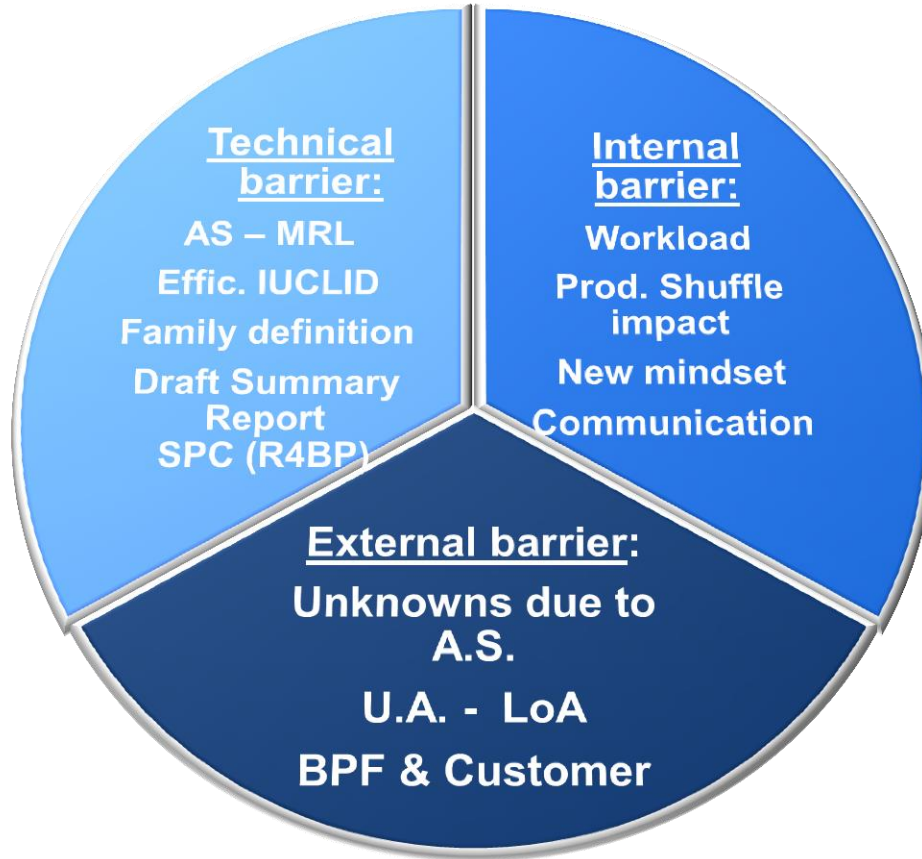
## Experiences

-  Shuffle of product range – unforeseens – choices – difficult understanding of criteria of BPF (limitation on innovation)
-  Add enforcement required -build up of dossier with intense dependency of R&D – right equilibrium N.A./E.A.
-  Put in place a working structure with RMS (2 directions)
-  Evaluate budget – working process – and find the right experience
-  Strategic considerations of customers should be taken into account
-  Use as much as possible infos build up in active substance dossier
-  Evaluate ownership of authorisation



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# Critical Issues & Barriers

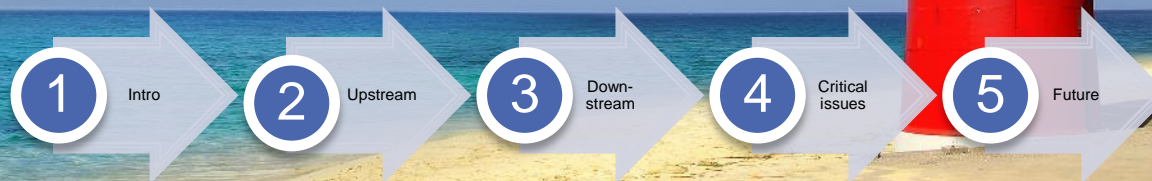


- Introduction
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- **Challenges for the future**

**Point of views:**

**CEO  
CCO  
Consultant**



**CEO:**

There is a fundamental belief in the mission statement of ECHA driving force → implementing EU Chemical legislation → benefit of health & enviro → innovation → competitiveness → role of support & information provider.

Care should be taken:

that invested money for achieving this “noble goal” contributes to competition by:

- a fair compensation if info-sharing is required
- avoiding free riding by non-fair players
  - putting in place “simple” “quick” procedures for extension of products + innovations within families in U.A.



**CCO:**

Speed of customer (market) decisions is high and price-product-service driven.

UA is very interesting principle but, the U.A. should take care about 2 concerns:

- 1) Submission dossier → validation
  - 2) Validation → end of 10<sup>th</sup> year
- Market-entrance should be guaranteed in countries where no N.A. was obtained upfront the dossier preparation. Innovation should be possible with a very easy, quick method within the family.





## Consultant :

Goal of a consultant: give a strong added value to companies in different areas of expertise.

Create added value is a cost for a company which needs to be very good balanced between administrative work and real added value.

Guidelines and supporting documents should be clearly defined to avoid useless costs for companies. (first time right = most efficient)

Short communication lines are important with authorities in case of doubts.







Thank you for your attention