AUTHORISATION UNDER REACH
5 Key Pitfalls to avoid to ensure a Successful Application

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REACH Risk Management
another way of looking to it…

REACH Registration

DE
- **DOSSIER EVALUATION**
- Checks generic compliance

SE
- **SUBSTANCE EVALUATION**
- Checks content quality, assumptions, combined volume,…

RES
- **RESTRICTION**
- Restrict certain uses, articles, … based on proven EU wide risk

AUT
- **AUTHORISATION**
- System of authorised use unless tech & economic feasible substitution is available

Authorisation

Its **not something to gamble about!**

It requires **careful attention and planning** to prevent….

5 Key Pitfalls to avoid to prepare for a successful Authorisation Application!

1. Define the **future** of the Annex XIV **substance**
2. **Organise** in time
3. Define appropriate **level of submission**
4. Invest in good **exposure evidence**
5. Build a case for a relevant **review period**

1. Define the “future of the substance”

MANUFACTURER

Is the substance of the future assured?

- Do I notice the potential for a substitute?
- May users substitute it?

Views and planning may be different

USERS:

- Do I have a substitute in mind?
- Will my supplier still supply me?

Start this excercise when substance is put on the Candidate List or when an RMOa is planned

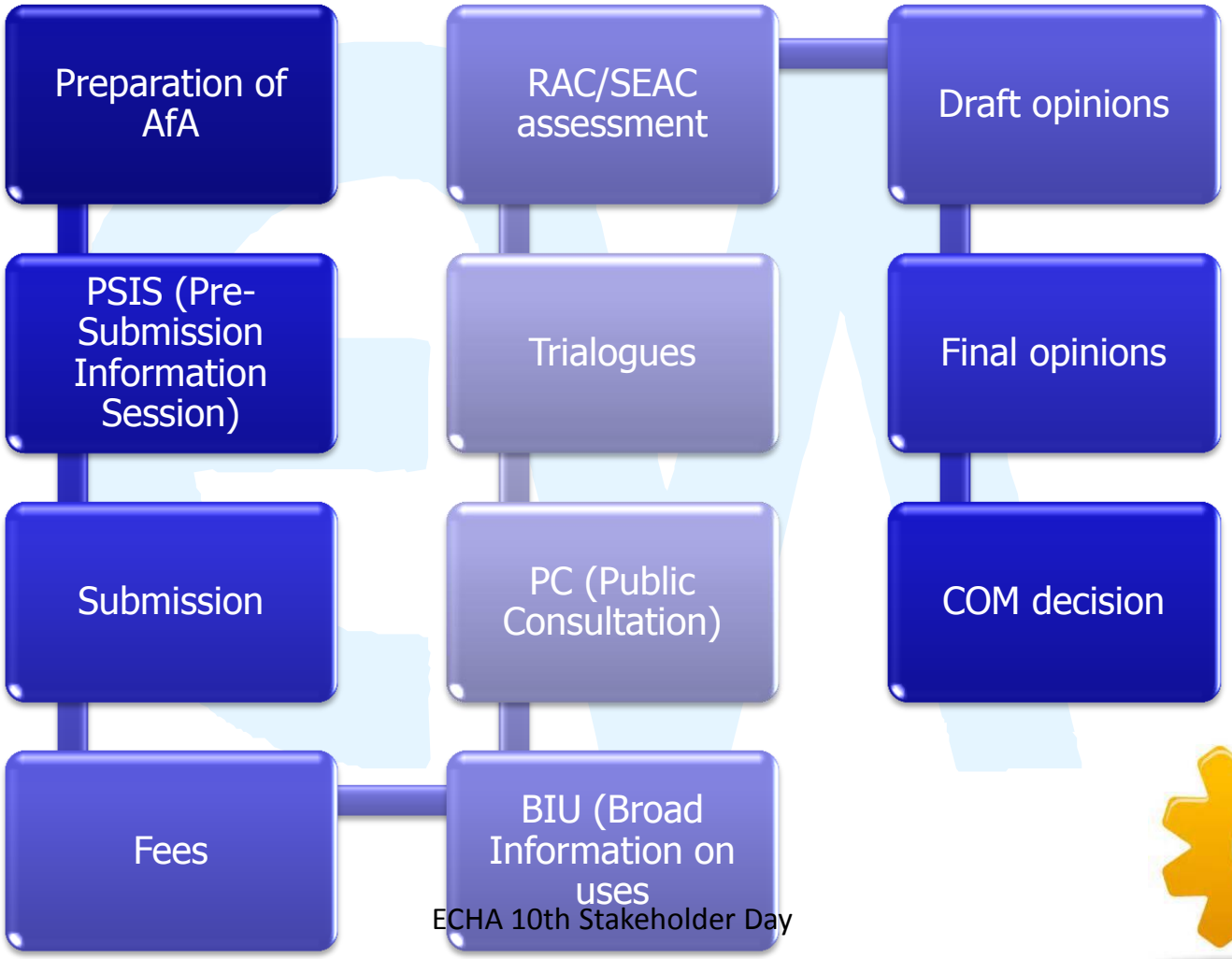
1. Define the “future of the substance”

- Final aim remains **substitution**
- BUT **Economic** and **Technical** Feasibility are considered

So a fragile BALANCE to strike between manufacturer & user

2. Organise in time

Understand all steps of the process and plan them well !!!



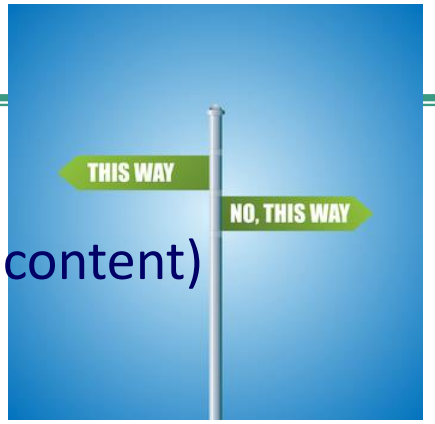
2. Organise in time

What to organise for?

- Do(n't) I prepare the AfA jointly?
- Do(n't) I set up a Authorisation Consortium?
- Do(n't) I have access to the CSR?
- Do(n't) I am for the Adequate Control or the SEA route?

Don't loose your LAD time for these!
Sort them out before the counting starts

3. Define level of AfA submission



At what level(s) do I apply?

(= not necessarily the same as preparation level of the AfA content)

Manufacturer / importer

Formulator | Formulator

Use X | Use Y | Use Z

Cheaper?

Easier?

- An Authorisation covers the **supply chain downwards** applied for
- **Upwards** it covers only 1 step

4. Exposure demonstration is key!

Do not forget to include **solid and verifiable EXPOSURE evidence**

Adequate control

-Demonstrate safe use

IN PRACTICE BOTH NEED EXPOSURE EVIDENCE

SEA route

Minimised exposure

5. And what about the Review Period

Either a period:

- **"To bridge"** until a planned substitute becomes technically/economically available

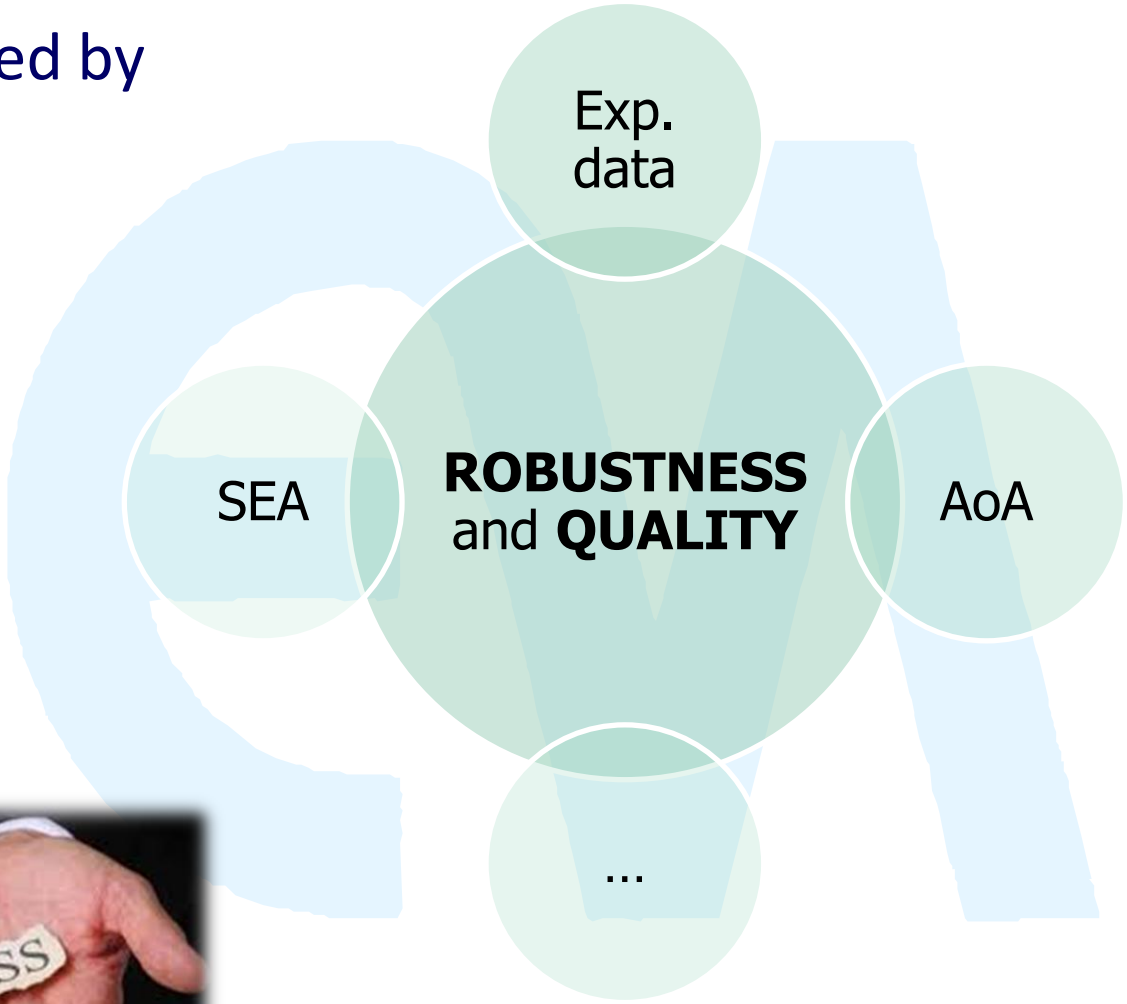
...Defined

- **To use** the substance and reconsider substitutes in the future

As long as possible...

5. Review Period of the Authorisation

Determined by



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And don't forget …

PREPARATION:

- Make use of **Annual AfA training** by ECHA and Cefic/Eurometaux
- Learn from **industry experience** (contact your sector organisations)

DURING the AFA submission

Use the exchange moments (PSIS, Trialogue, …)

Conclusions

- Submit an AfA when convinced **you need it**
- Prepare and plan **on time**
- Keep the AfA **focussed, robust and clear**
- Take the 5 **potential pitfalls serious**

And even…