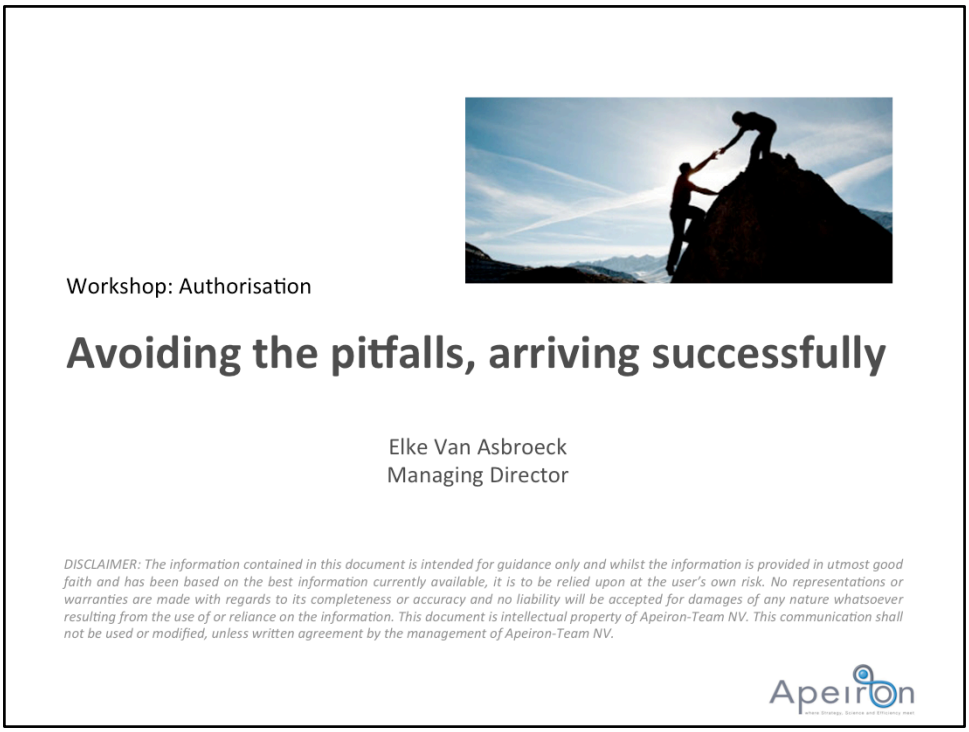
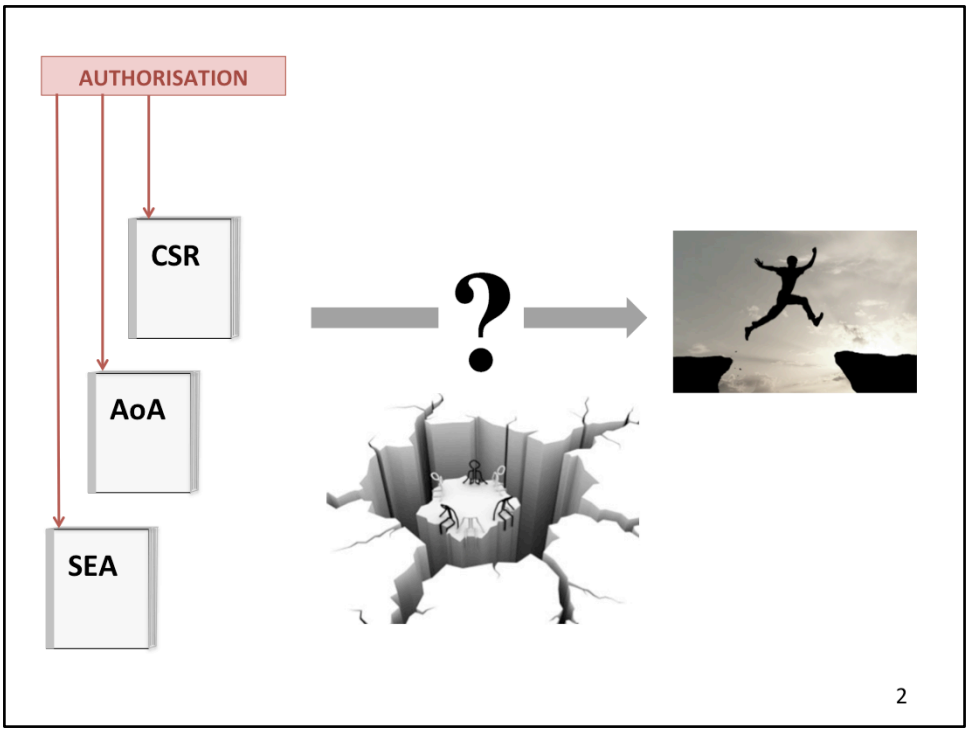


ir. Elke Van Asbroeck, Managing Director of Apeiron-Team NV.
Before we founded this consultancy firm, I've worked in industry for 12 years. More specifically in the waste & recycle industry and in the polymer industry in various positions.

I want to share with you our insights in the authorisation process with regard to the work we did in

- the Vlisco case on TCE, a non-threshold carcinogen. It concerns textile industry where we made a justification for 12 years and recently received a draft opinion for 12 years, and

- the Parker case, also on TCE. This was for an aviation application. We are anxiously awaiting the draft opinion.



You are using a substance that recently came on the authorisation list.

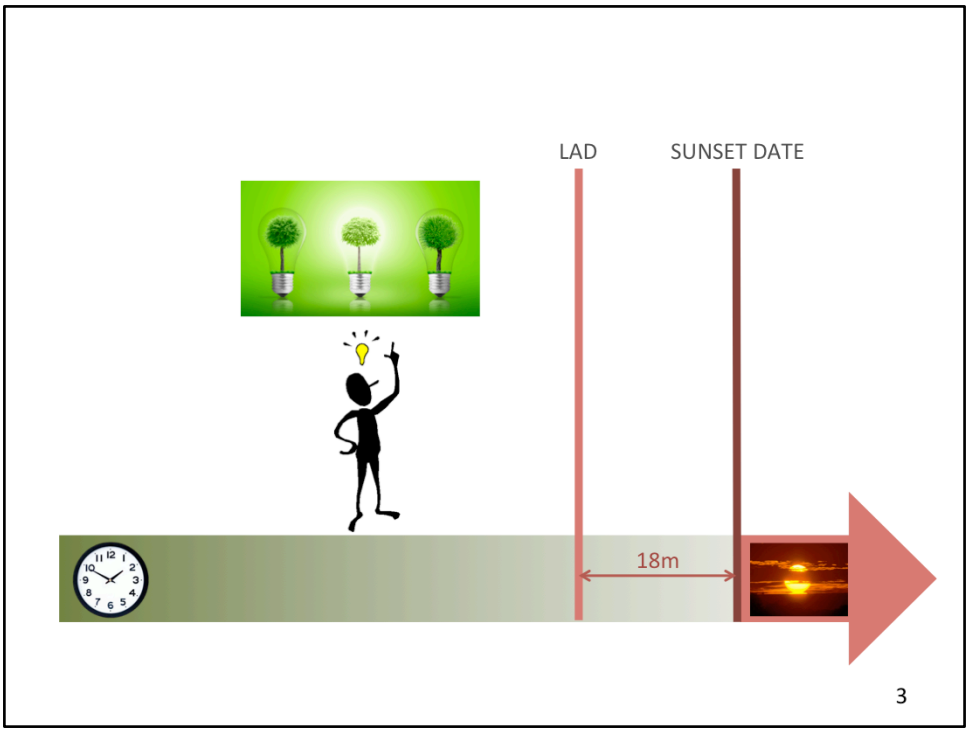
You will have to prepare 3 documents:

- A Chemical Safety Report
- An Analysis of Alternatives, and
- A Socio-Economic Analysis

Arriving successfully by anticipating the pitfalls:

- How to proof minimization of emission?
- How to make the economical analysis? (use profits or revenues?)
- How to define a CREDIBLE non-use scenario?

Before you decide to go for authorisation, consider this…



Potential alternative in the pipeline?

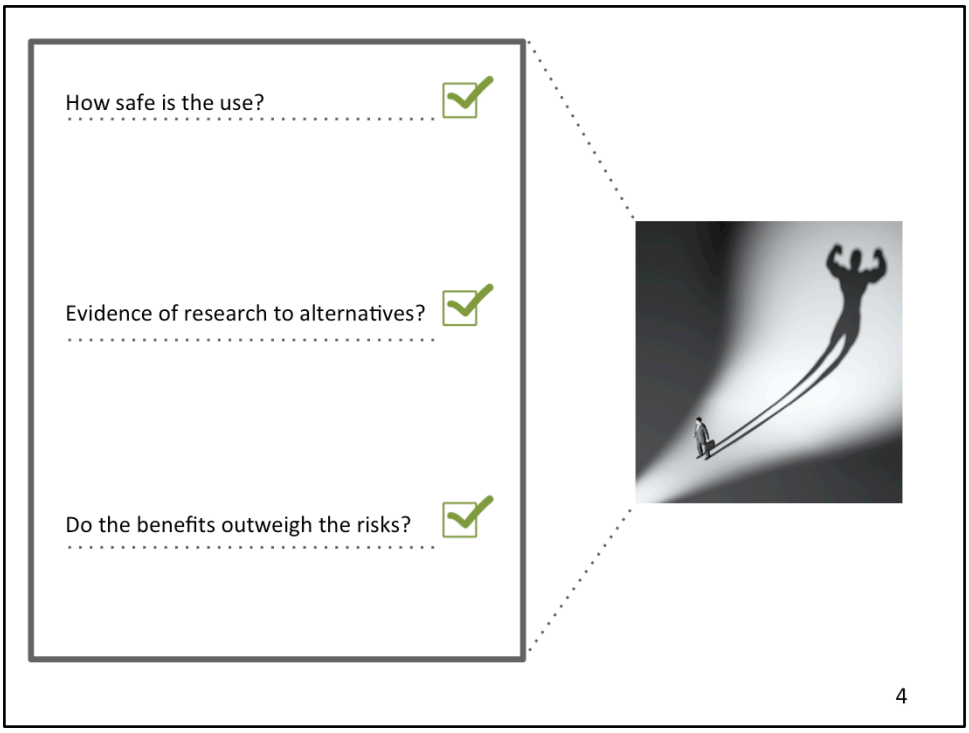
- When can you have it installed?
- Cost comparison

We make this assessment together with our clients.
This is done during the first strategy meeting:

The goal of this meeting is to get the strengths and weakness of the case on the table. These are the main elements for the CSR, AoA and SEA.

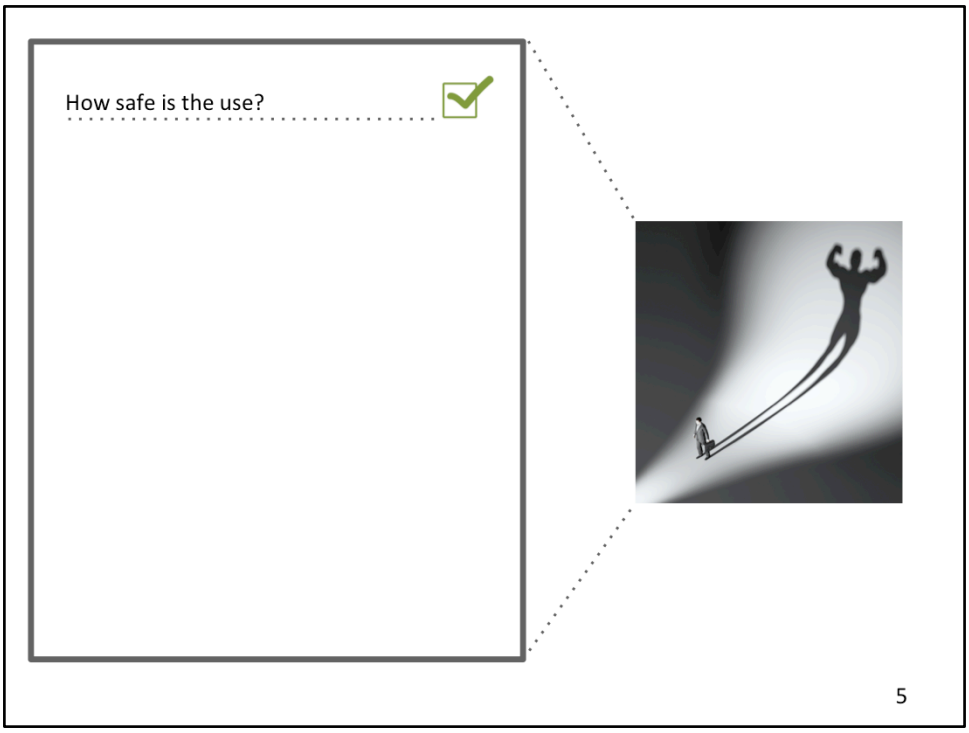
In 2 cases this strategy meeting has led to the decision not to go for authorisation.

But what makes a case strong?
Which elements do we look at?
Answers to these questions, provides insight in the cost of the project.



What makes a case strong?

1. How safely do you use the substance?
2. Is there evidence of a research program? Can you proof there are no suitable alternatives?
3. Do the benefits outweigh the risks?



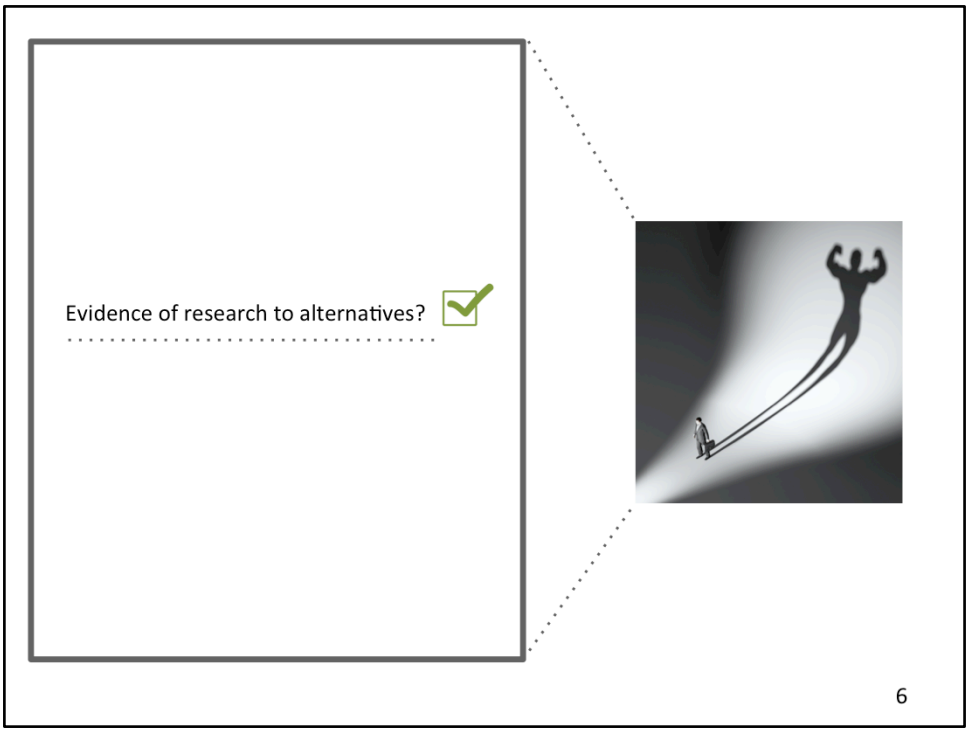
With regards to SAFE USE:

- Demonstrate that exposure is significantly below the threshold or, for non-threshold substances like trichloroethylene, that emissions are minimized.

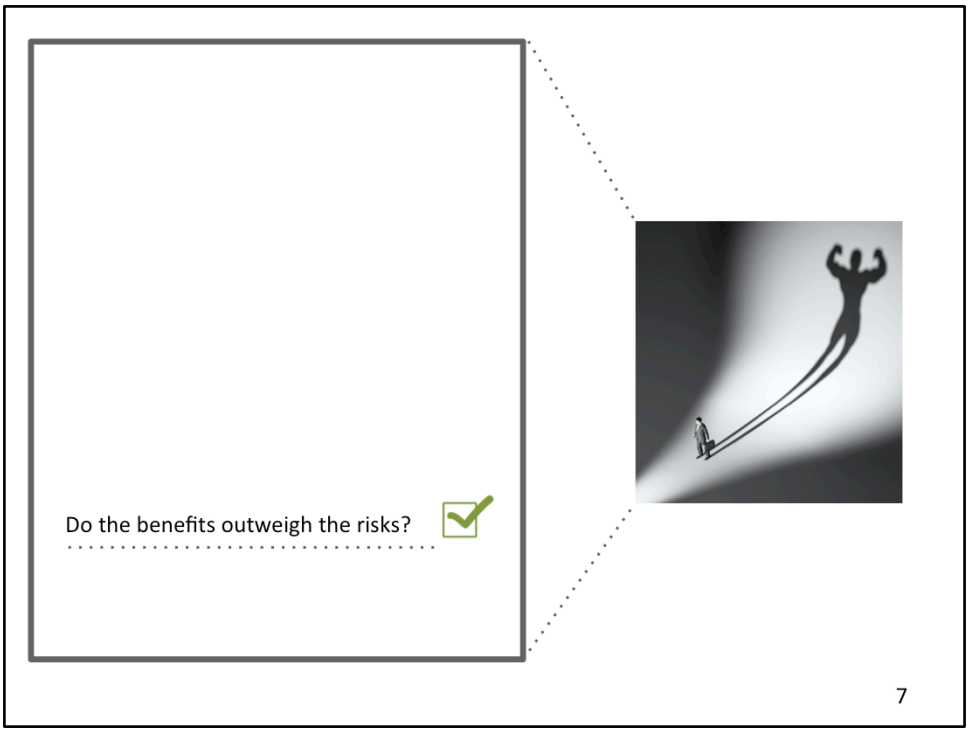
- Demonstrating minimization of emissions takes more effort, because neither the regulation, nor the guidances provide a definition or criteria for “minimization of emissions.”

- In the cases of Vlisco and Parker, we provided:
    - Monitoring data for workers and environment
    - Data for man-via-the-environment
    - Data that proofs that there is no exposure to consumers

- On another note, the RAC opinion on threshold/non-threshold is of great help to DUs. Moreover it saves costs during the dossier building. Remark: please provide it as of the moment the substance is included in Annex XIV, because the opinion on threshold or non-threshold forms an important element to define the cost of the case.



During the strategy meeting, the main elements of the AoA are discusses and assessed on their strength.

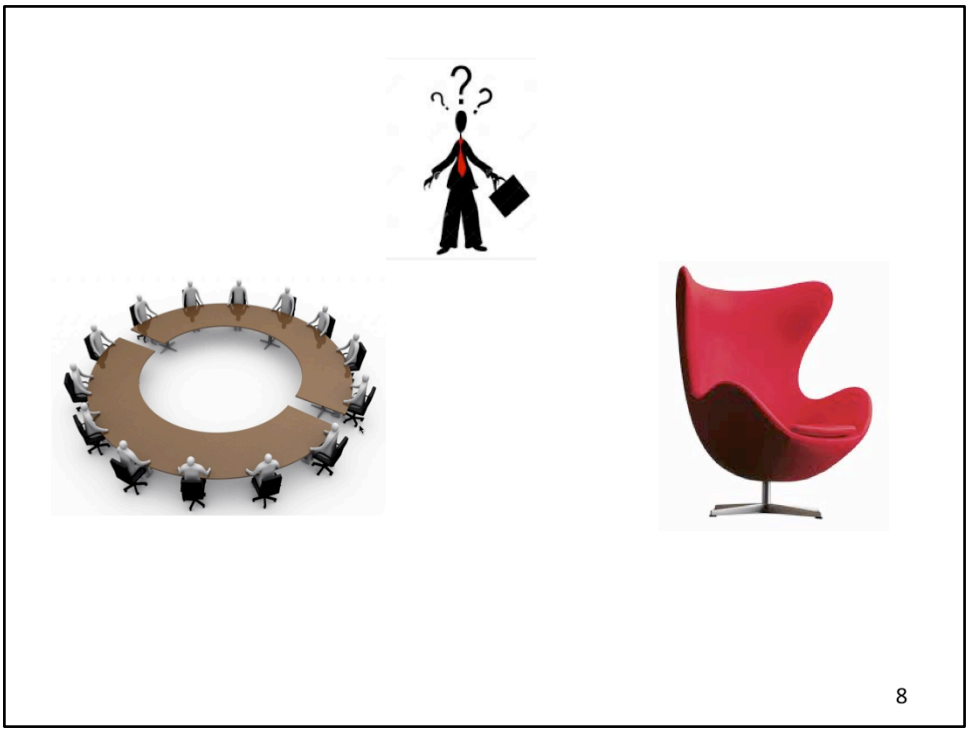


In laymen's terms:
Is the cost for society, to stop using the substance after the sunset date higher than the cost of health/environmental risks?

This means that the strength of the SEA depends on

- The credibility of the non-use scenario
- The quality of the data

Thus, during the strategy meeting, the main elements of the CSR, AoA and SEA come on the table.
This drives the decision to apply for authorisation or not.



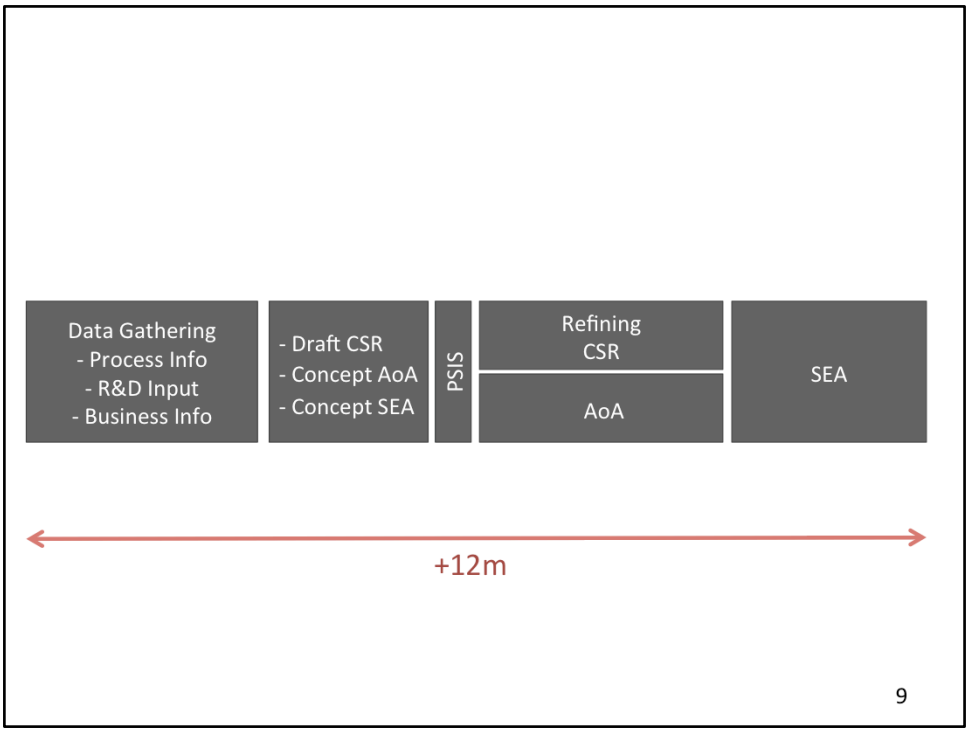
We have decided to go for authorisation...
with partners or solo?

It is obvious that the benefit of “going with partners” is the cost split.
But, is this right way forward for you? Consider this:

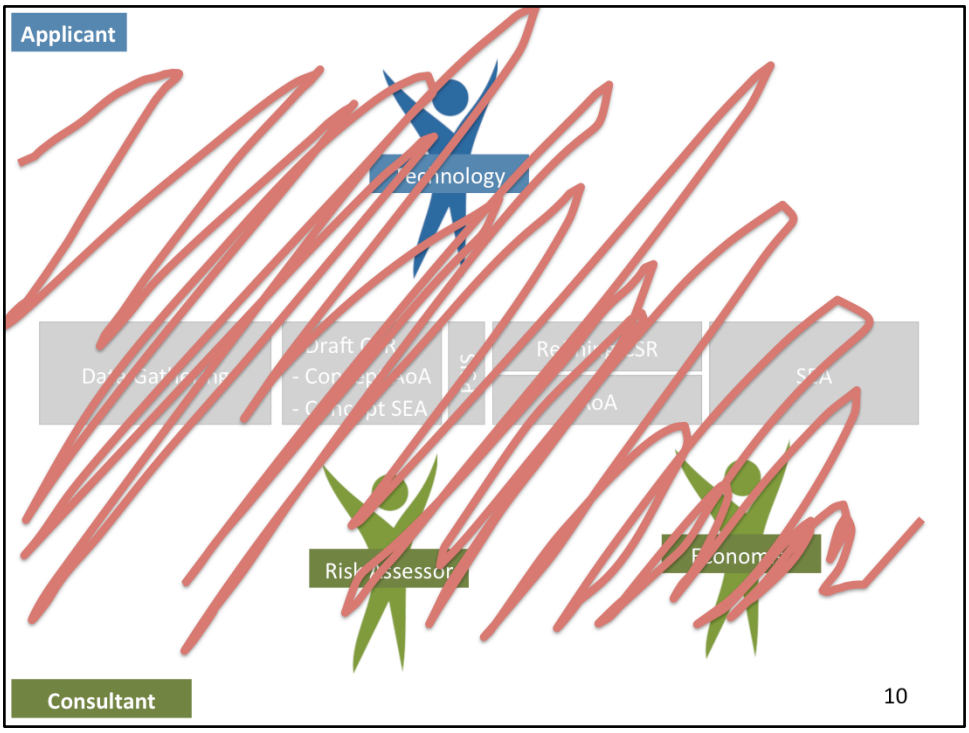
- What is the time and cost for contractual discussions?
- What is the time and cost for meetings to agree between applicants?
- What is the cost for the trustee, to avoid competition law infringement
- But most of all! How does this influence YOUR chance to success?
  Because all the partners have to comply to the conditions described in the dossier, the dossier has to be based on the worst case of the group.

From a positive perspective: this creates an equal playing field, BUT...
You step into the process blindly and only after about 6 months you will know whether the group effect is positive or negative for you.

In the case of Vlisco and in case of Parker we described the real situation on site. (they went solo). This helped in presenting clear and transparent case.



- We need to gather data
- We prepare:
  - ✓ Draft CSR
  - ✓ Concept AoA and SEA
- Then we send this to ECHA 1 month before the PSIS meeting
- After the PSIS meeting
  - ✓ The CSR can be finetuned
  - ✓ The AoA and the SEA are written
- Total time is ca. 12months. Shorter is possible, but is not recommended. Why? It is important to gather the correct data in the beginning to reduce the number of iterations in the calculations. This results in an overall lower cost for the dossier generation. An example: ideally the impact assessment of the SEA is made after finalization of the CSR. Indeed, the exposure results from the CSR are used in the impact assessment of the SEA to calculate the costs of continued use.

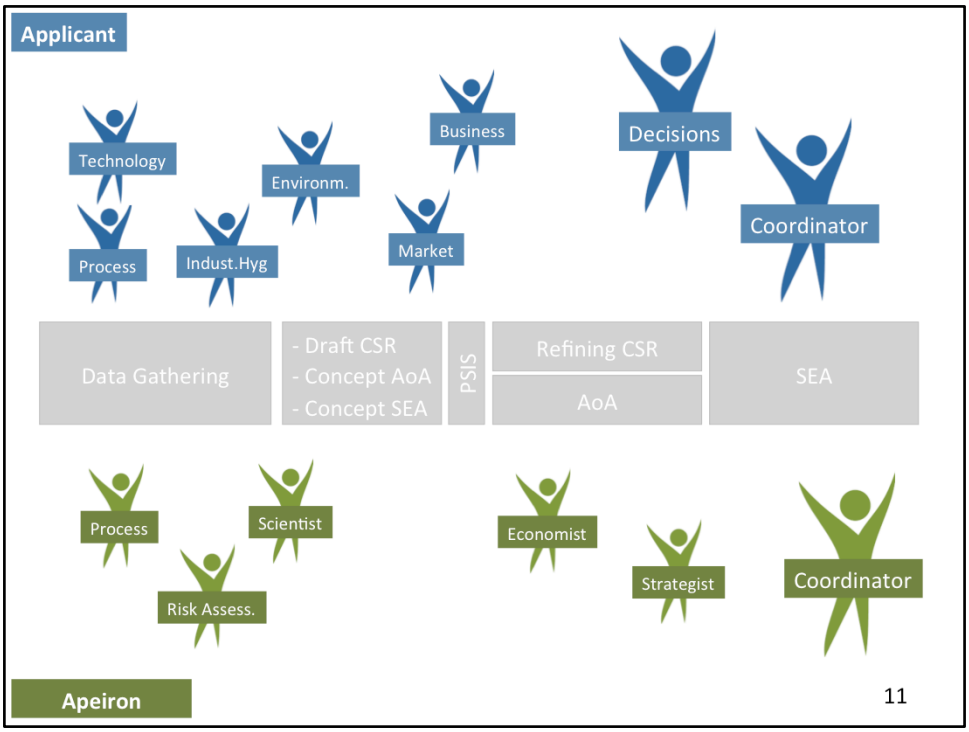


Who do you need in the team?

Typical industry reaction:

- Internal senior technologist, and
- Consultant with a risk assessor and economist

This model does not work.

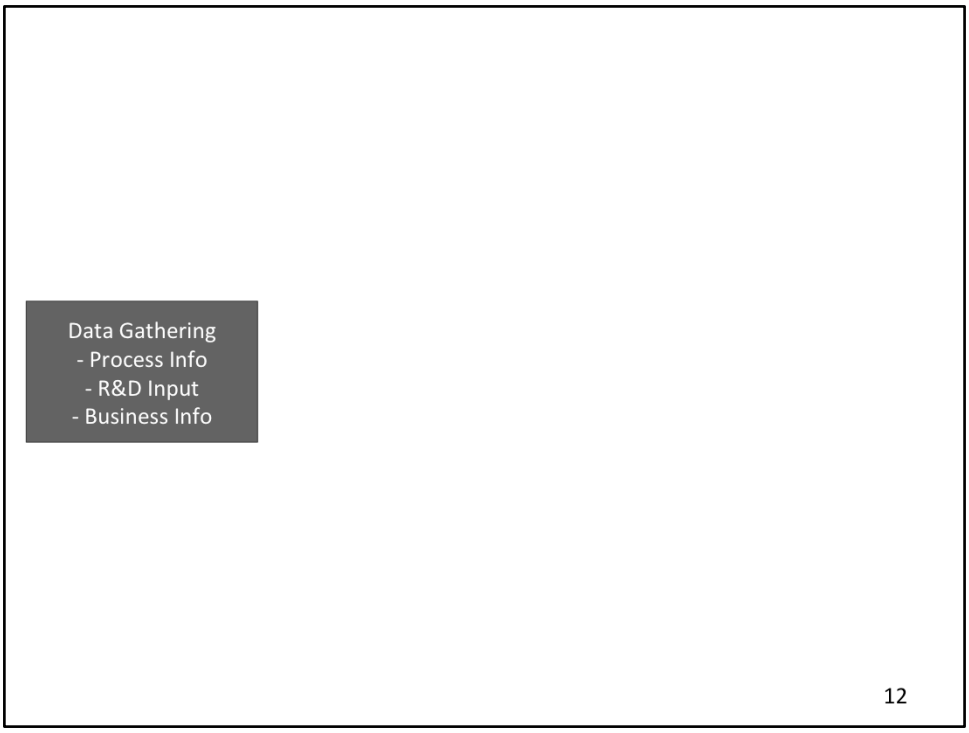


You need a TEAM with several competences (see slide).

(one person can tackle several of the competences, but it is clear you need a team and not just one person to make a thorough dossier).

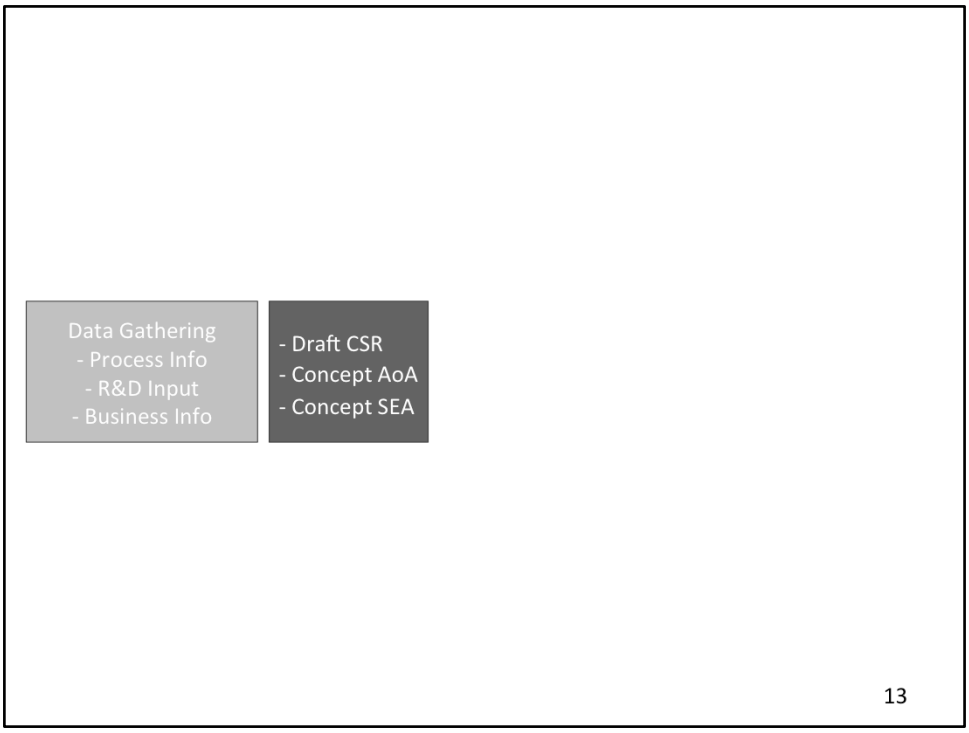
What is the added value of your consultant?

- We identify the blind spots. We take the role of the committees before they do…
- We translate the highly technical and economical information in a language relevant to the committees.



It all starts with gathering the necessary data for:

- CSR
- AoA
- SEA



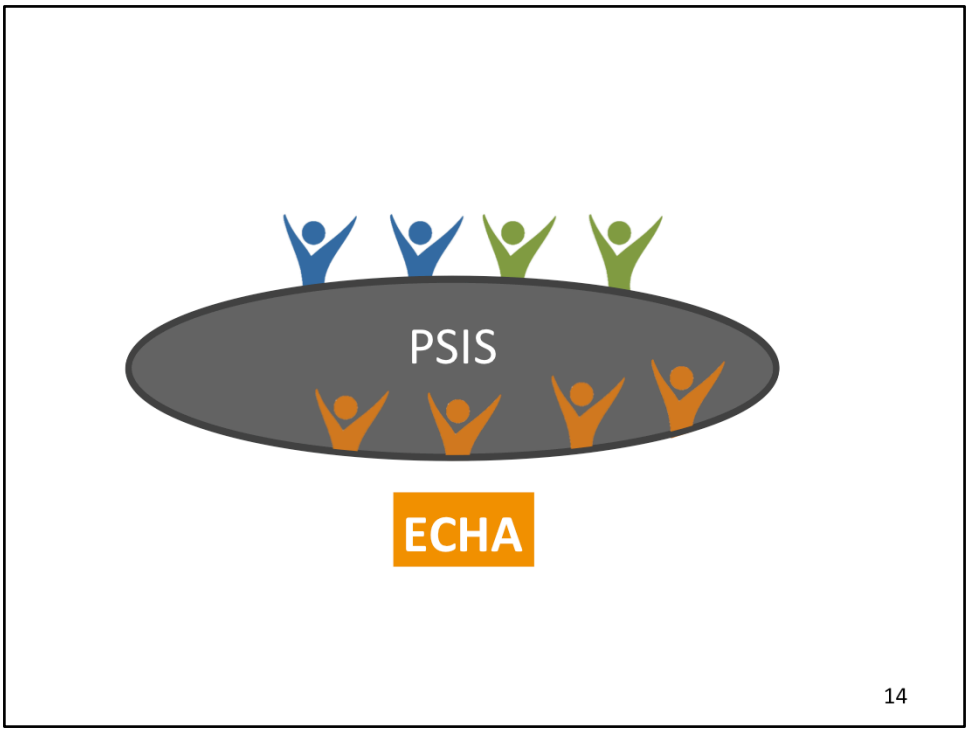
From the data set, we

- Draft the CSR

- Generate a concept AoA. This is everything in the AoA, but not yet the detailed assessment of the alternatives in the short list. We wait with this until after the PSIS to avoid re-work and hence to reduce the overall cost of the dossier building.

- Generate a concept SEA. This is everything in the SEA, but not yet the impact assessment. We wait with this until after the PSIS to avoid re-work and hence to reduce the overall cost of the dossier building.

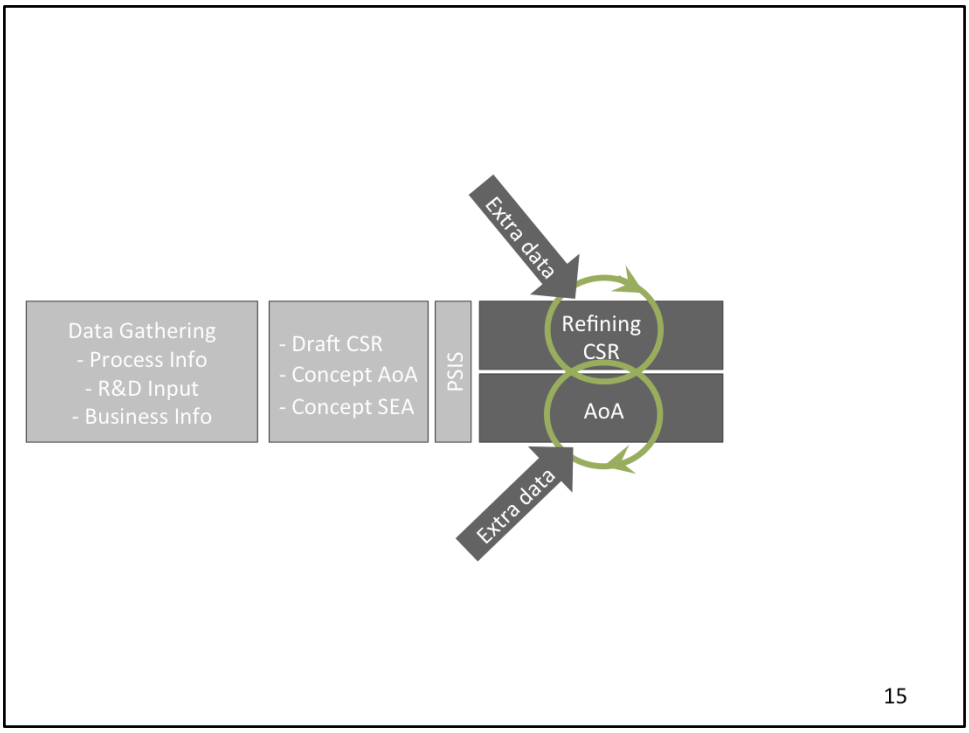
Then we submit all this information to ECHA, 1 month before the PSIS meeting.



The Pre-Submission-Information-Session: applicant – ECHA

This meeting is not obligatory… but GO!

Remark:
if you send good quality documents to ECHA, ECHA can give good hints, still in time to gather extra data and include them into the dossier.

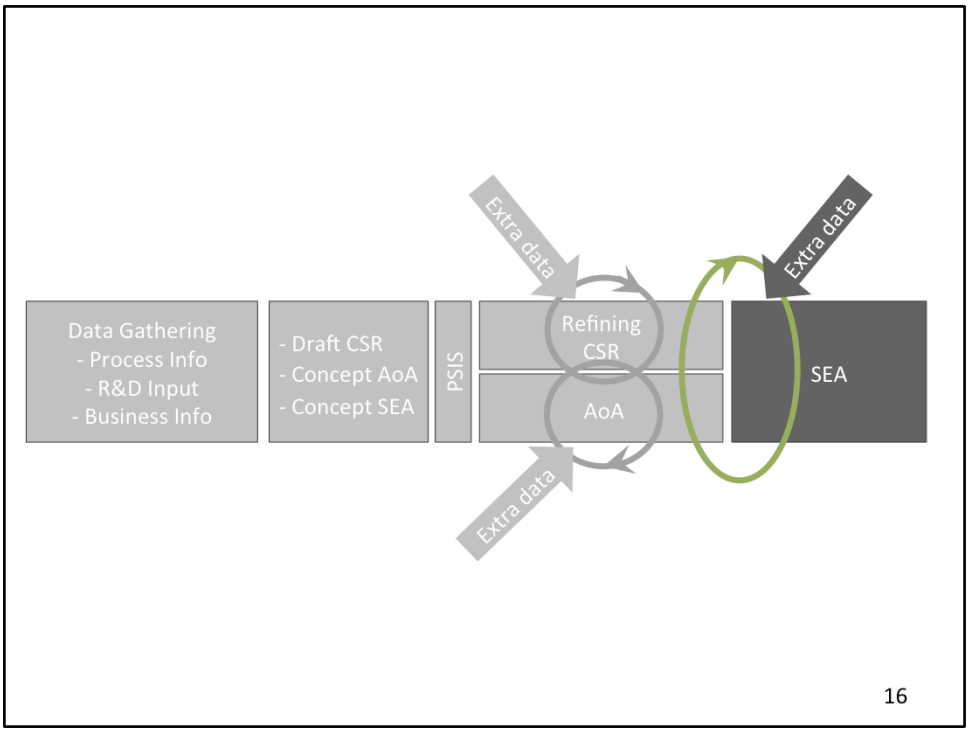


After the recommendation from ECHA

- The CSR can be fine-tuned with extra data

- And for the AoA:
  - ✓ We awaited the PSIS to avoid re-work and hence to optimize the cost. Indeed, after the PSIS we know that ECHA follows our reasoning to arrive from a long list to a short list of alternatives.
  - ✓ Assessment of the (1) risk, (2) technical feasibility, (3) economical feasibility and (4) availability
  - ✓ Identification the most likely non-use scenario.

Remark: these are iterative processes.

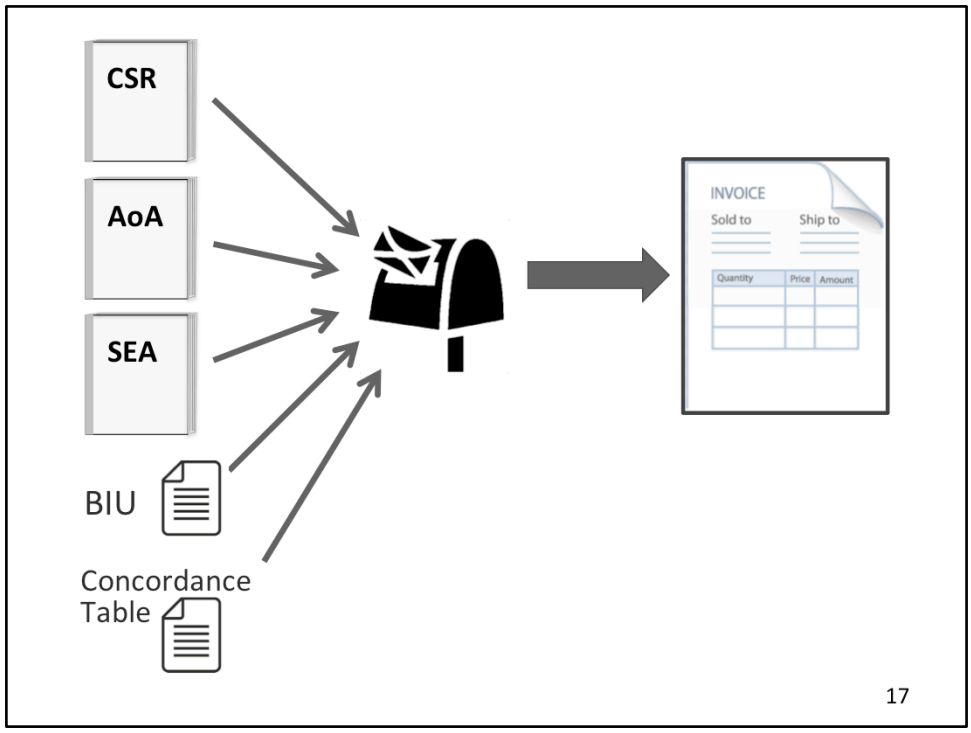


The concept SEA was made. Now we make the impact assessment for society.
To do so, we use

- The exposure levels or excess risk levels from the CSR
- The non-use scenario defined in the AoA

- It is therefore logic that the impact assessment is done after finalization of CSR & AoA. This to avoid unnecessary re-work and hence to avoid increased costs for dossier building.

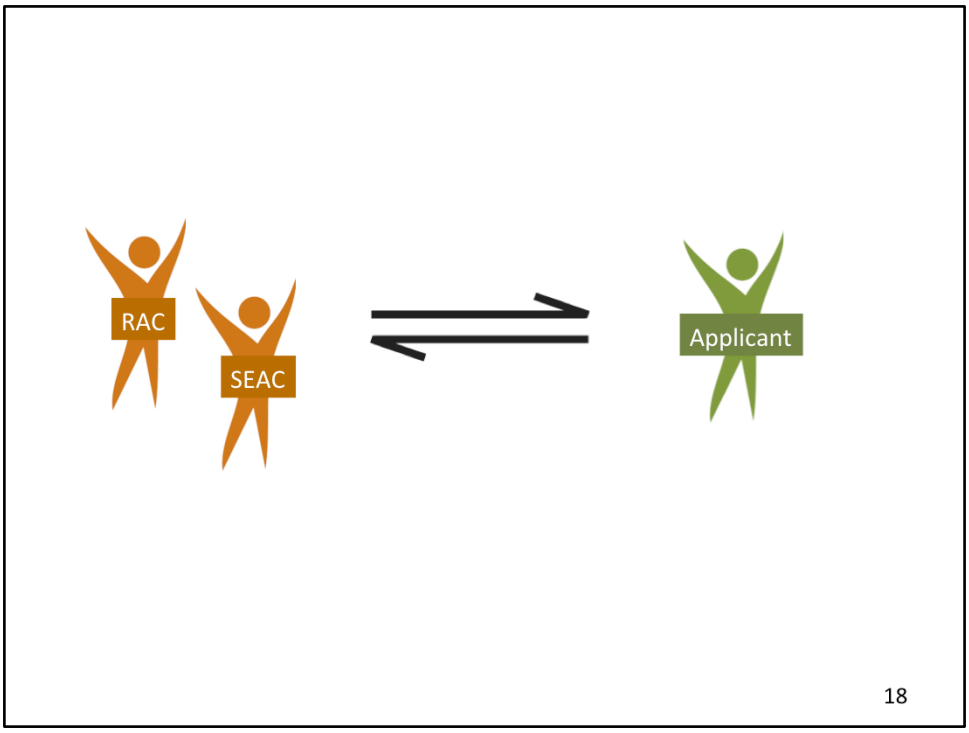
- Also the impact assessment is an iterative process.



The dossier is ready…we can submit.

About 2 months after submission, you will receive the invoice which you have to pay in 2 weeks time.

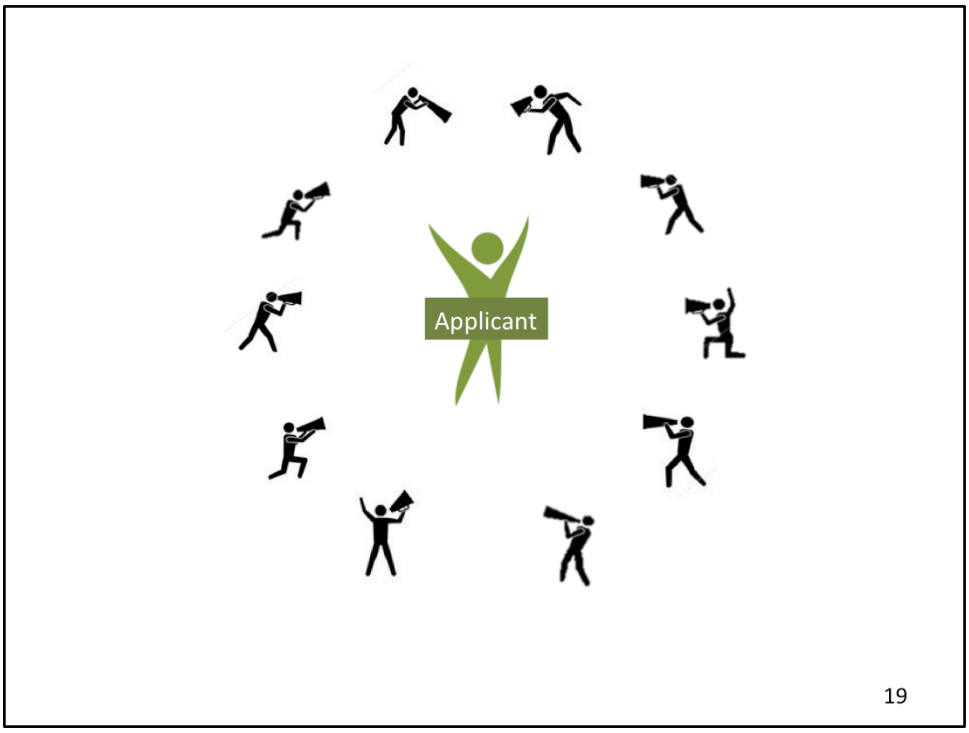
Once paid, the submission is final.



Plan your resources well ahead because about 2 months later you will receive the first group of questions. These come from RAC and SEAC.

We did not answer them lightly.
We took the cost and energy...and it did pay off.
Because we were so thorough, RAC and SEAC decided a trialogue was no longer needed.

This saved us 6 months time in opinion making and on top of that, it saved costs.



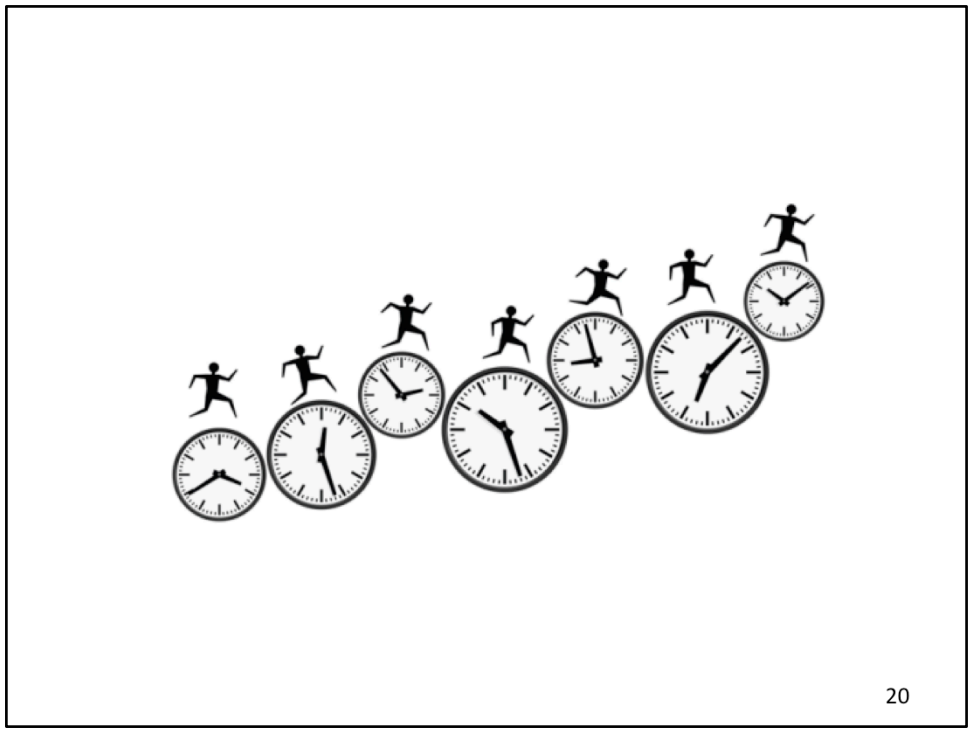
Almost at the same time, the second group of questions arrive: from the public:

On the ECHA website you can find cases where more than 200 comments were made. For instance, for leadsulfochromate.
some of the the comments were duplicates, but still!
you have only 2 weeks to analyze them and respond...

For the Vlisco dossier and the Parker dossier, we have not received any comments from the public.
In our dossier we anticipated the concerns from the stakeholders.

Not receiving comments from the public was another important element why RAC/ SEAC decided that a trialogue was no longer necessary.

At this moment, our work was done. All that was left was waiting...



RAC / SEAC have 10 months, to evaluate your dossier (draft opinion).

It is in our own interest to help them digest the truckload of information.
We have done this, by providing a dossier that is:
To the point, Clear,Transparent, and Credible. This is the opposite of defensive.

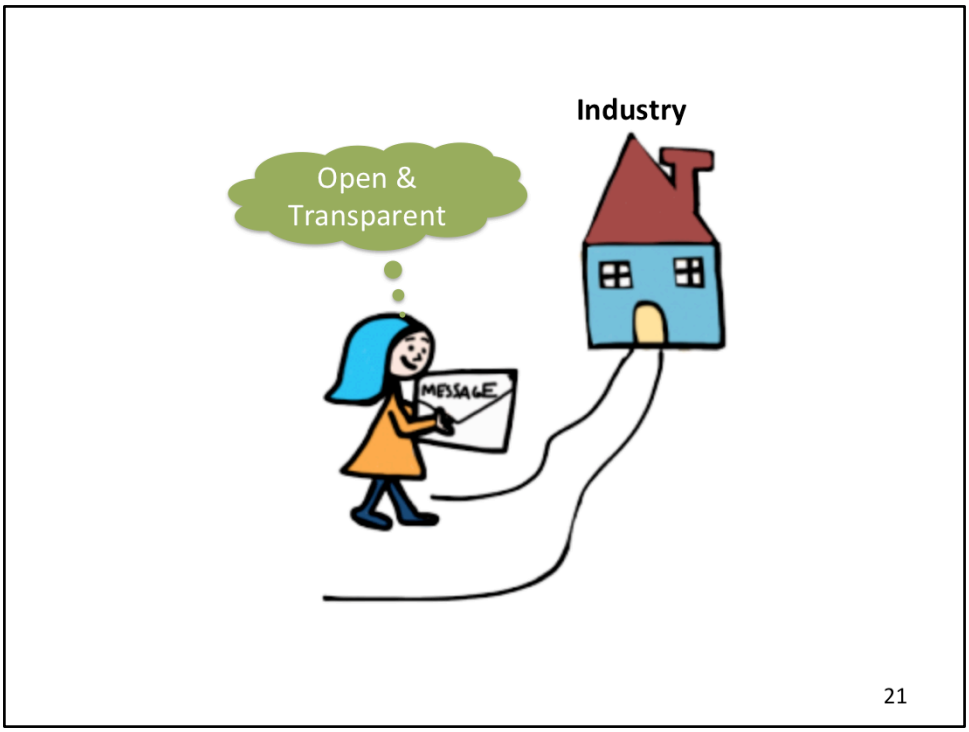
As a result, we received a positive draft opinion after only 4 months for 12 years

Why was an early draft opinion important to us? It is simple: The authorisation process is “business disruptive”. Industry has only one chance, which is unsimilar to any other legislations. Without certainty of business continuity:

- no large investments,
- no budget for innovation in the long term,

For Vlisco in particular:

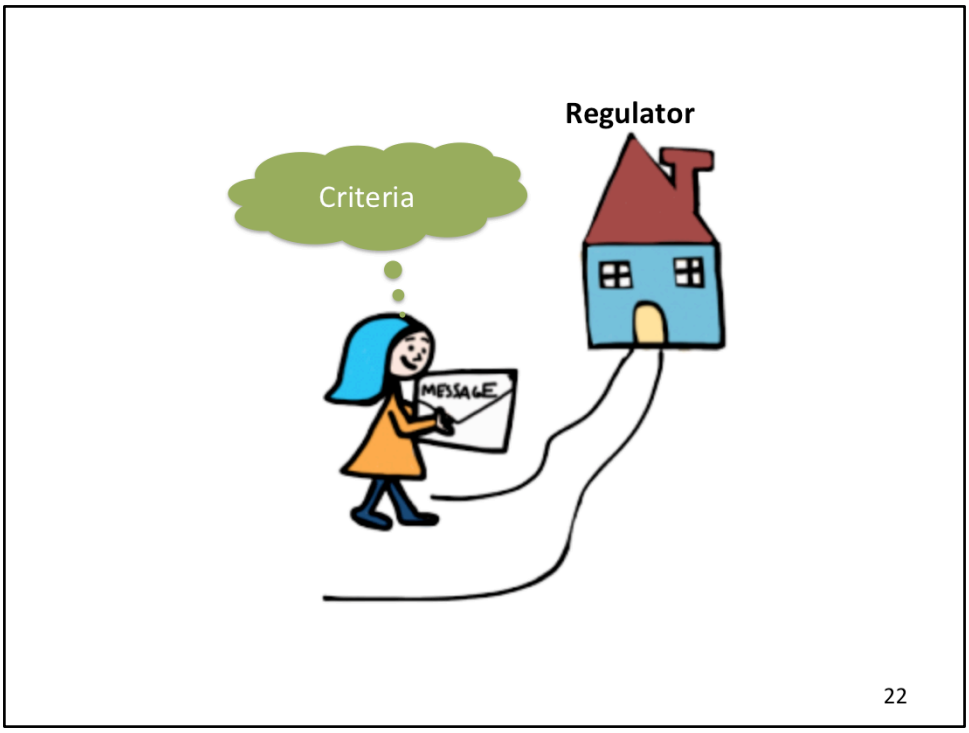
- Vlisco was for sale. Who wants to buy a company that cannot guarantee business continuity?
- As long as the draft opinion is not available, Vlisco did not know whether the future would be (1) implementation of the non-use scenario or (2) starting the research for switchable solvents. A promising and innovative technology...what the authorisation process is designed for.



Take home message for Industry:

You have a strong case, otherwise you would not apply.
So why would you have to go in the defense?

We took the approach to be as open and transparent as possible.
And it worked.



Take home message for the Regulator:

Help us to provide you the right balance of information:

- What are the specific criteria you use to define the length of a review period?

Which elements do you want to see in the dossier?

If you could give us clear criteria:
Industry could be more accurate and efficient in providing high quality dossiers, and
It would safe RAC/SEAC time evaluating of the dossiers.

For the regulator: main messages mentioned in the presentation were:

- RAC opinion to be available as of the Annex XIV publication
- Minimization of emissions: RAC, which elements do you want to see?
- RAC/SEAC: The requirements seem to increase instead of decrease. Can you tell us what you don't need, so that we can reduce the cost of dossier building?
- RAC/SEAC questions: can be "interpretable". Request to explain the question and the reason behind the question by phone → will lead to more accurate answers and efficiency increase for both parties

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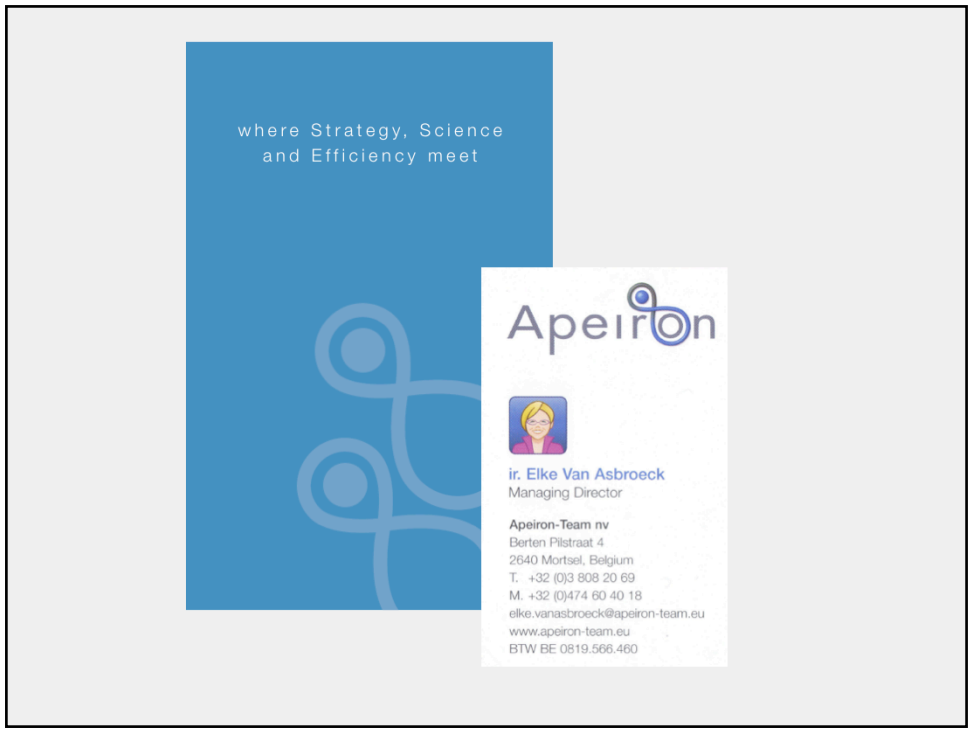
So basically...
The message to industry and the regulator is the same:
Make it TRANSPARENT !



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