Need a SEA? What to do?

L'analisi socio-economica nel Regolamento REACH

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  - To provide input to the restriction
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Why do you need a Socio Economic Analysis ?

Why do you need a Socio Economic Analysis (SEA)?

- **Regulatory Context**
  - SEA is a **tool** to support decision making (REACH Restriction/Authorisation)
  - To evaluate the relevant impacts (HH, Env, Social and Economic) on the different scenarios proposed.
  - According to the context – SEA will be prepared by authorities or companies.

⇒ **In any case, companies input is more than welcome to base the SEA assessment on concrete data.**

⇒ **Quality data meaning better quality assessment**

Why do you need a Socio Economic Analysis (SEA)?

- **Added value to develop a SEA**
  - To provide a broader picture on the **economic impact** the regulatory measure will have on the society and the market of impacted industry sector/companies.
  - To demonstrate the cost to implement the regulatory action will remain **proportionate** to the benefit expected from this action.

⇒ **The cost benefit analysis will allow to evaluate whether the objectives described in the proposal will be achieved in the most cost effective way**

Why do you need a Socio Economic Analysis (SEA)?

- **SEA should be performed for**
  - **NON threshold** substances – non threshold CMR substances - PBT/vPvB – some Equivalent Level of Concerns => SEA route
  - **Threshold** substances for which adequate control of the risks cannot be demonstrated.
  - To provide insight for the setting of **Review Period**.

=> SEA plays an important role in the decision process!

- **Added value to develop a SEA**
  - To provide **additional details** on
    - *economic impacts* – based on Chemical Safety Report and Analysis of Alternatives
    - *economic feasibility* of alternatives based on the Analysis of Alternatives

Different Regulatory Context

Different Regulatory Context

	Restriction	Authorisation
• Who?	• Authorities – MS/ECHA (upon EC request)	• industry
• Targeted chemicals	• Any substances for which there is an unacceptable risk requiring a Community wide basis action.	• Candidate list substances included in Annex XIV – CMR, PBT/vPvB, ELoC

• Scope – level of details
• Impact assessment
	• Defined by authorities
	• Not all impacts considered
	  • SE impacts MAY be analysed
	  • Net benefits to HH/Env of the restriction MAY be compared to its net costs to M,I, DU, distributors and society as a whole
		• Defined by applicant
		• Relevant impact considered should match with authorities expectations – HH/ENV – workers, consumer, general population, society, company. For all relevant uses.

• Regulatory context	• ECHA opinion shall consider SE impact of the restriction, including the availability of alternatives	• The COM NEEDS SEA information to grant afa = B>Risk to HH/Env arising from the use of the substance
		• Assessment of data provided in the application.
		  • SEA data MUST be provided to develop SEA route afa
		  • SEA data MIGHT be provided to develop AC route afa.

• Alternative assessment	• It shall be considered in the opinion	• AoA MUST be considered
• Assumptions	• Based on available data	• Provide realistic scenarios

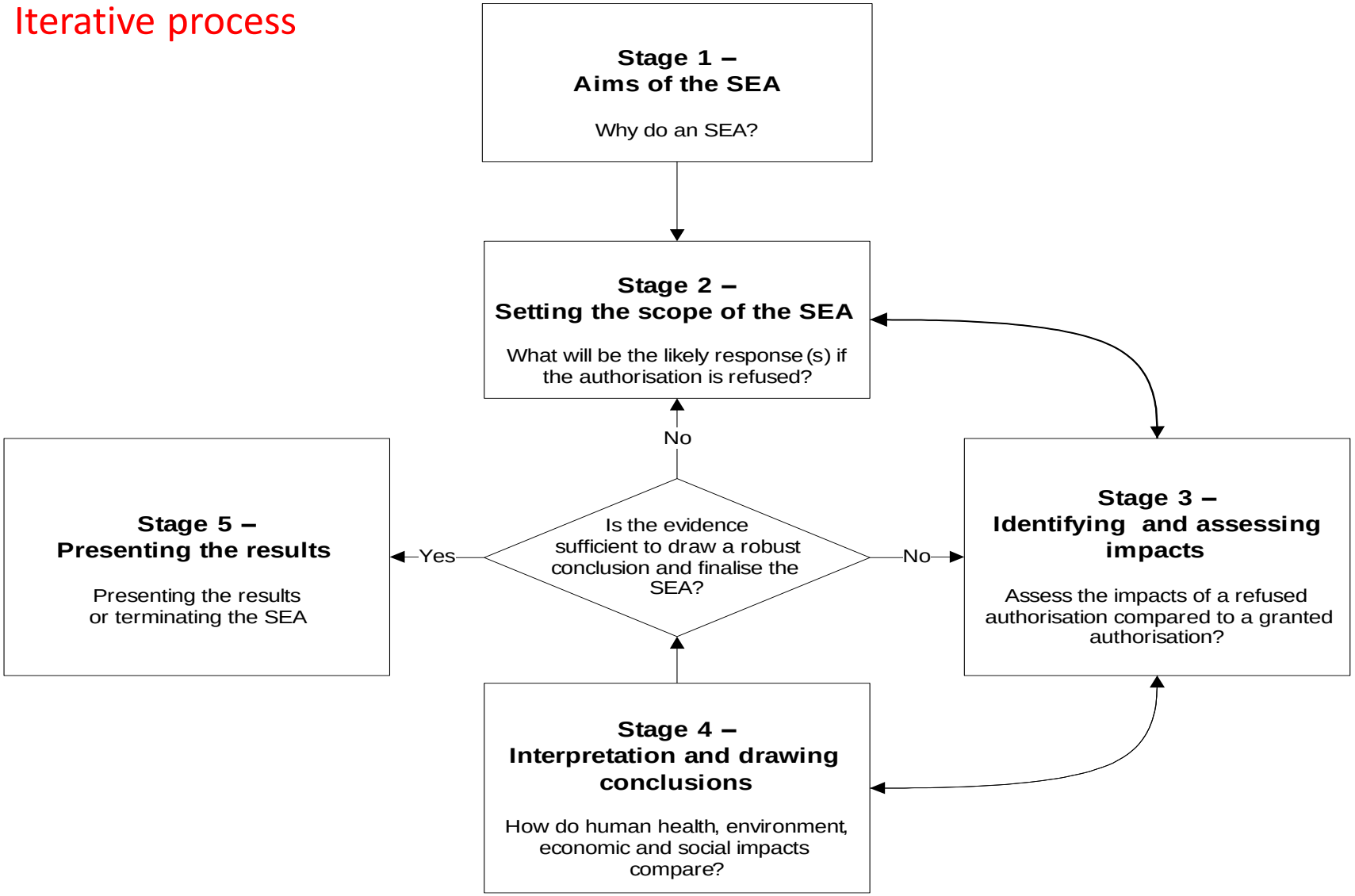
Different Regulatory Context

- **REACH Restriction vs REACH Authorisation**
- Similar SEA requirements for proposed restriction or authorisation
- BUT the objectives is to show 2 different scenarios
  - Restriction => use permitted unless banned
    - Annex XV refers to the NET benefits to HH and Env of the restriction compared to its NET cost to manufacturers, importer, downstream users, distributors and society as a whole.
  - Authorisation => Use banned unless authorised
    - Art 60(4) authorisation may be granted is it is shown that socio-economic benefits (of continued use of the substance) OUTWEIGH the risk to human health or the environment arising from the use of the substance.

SEA dossier preparation

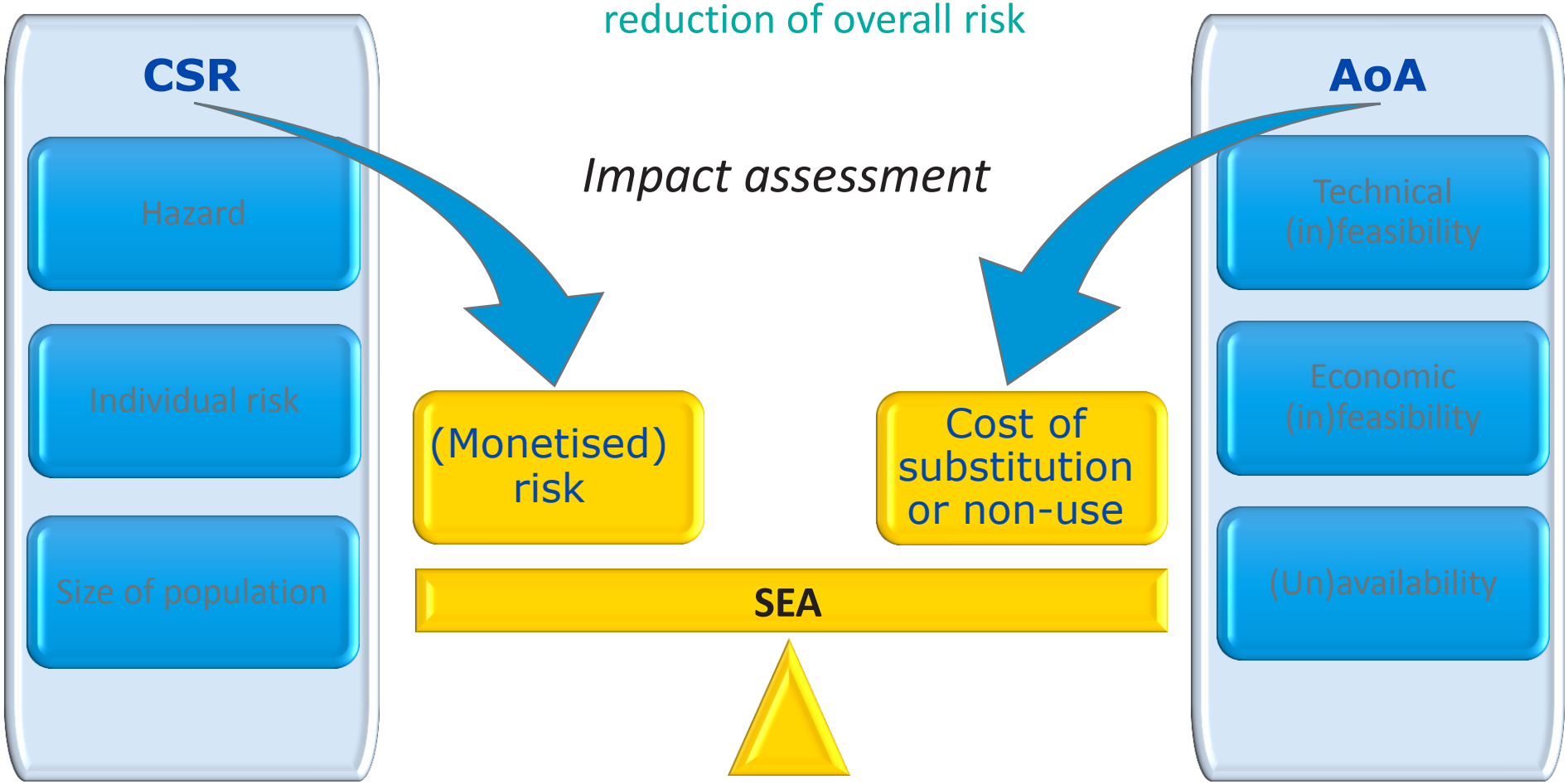
OVERVIEW of SEA PROCESS for authorisation

Iterative process



SEA dossier preparation for authorisation

- **Link with CSR and AoA** - remaining risk, potential safer alternatives, reduction of overall risk



SEA DOSSIER PREPARATION

- **How to prepare a SEA dossier? What? By whom? When?**

WHAT

- **Aim** = Need to explain why you need to develop a SEA? Aim?
- **Scope** = Need to define witch use is covered ?
  - baseline = business as usual – what is the "targeted use"
- **NUS** = Need to present the different options in response to the restriction proposed or the authorisation (non use scenario)
  - Which supply chain, sector is impacted
  - What is the impact on society as a whole?
- **Frame** = Need to determine the spatial and temporal boundaries = geographical limits (local-regional - EU – non EU) and period of time considered to evaluate the impact.
- **Impacts Estimation** = Need to estimate - to monetize- the health and env impacts, the economic impacts of the proposed measure
- Need to consider also the distributional social impacts

=> in any case, need to summarise all the data – structure the analysis and explain the assumptions made in a way it can be understood.

SEA dossier preparation

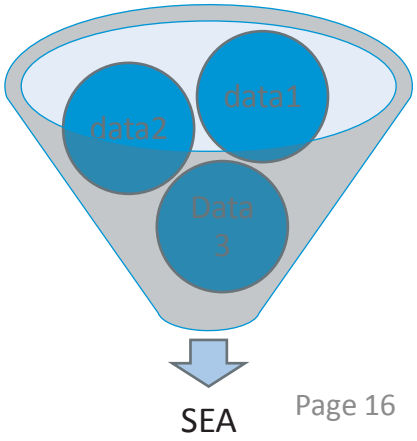
- **Description of the impacts due to the regulatory measure**
- Authorisation – **Non use scenario**
  - What is the **most realistic non use scenario** (NUS)?
  - What will the **company do** (in terms of production, development of alternatives, etc) if it can no longer use the substance?
    - Detailed the **most likely alternative** with technical implications, estimation of value costs, etc.
    - Changed **quality** of the products or processes (e.g. reducing concentration of the substance) – technical changes required, financial implication, impact on business..
    - **Cease activities** in this market – services no longer provided – relocation of product activities outside of EU – impact on business, estimation loss of revenues, job losses, value costs, type of product no longer available to end user, function no longer fulfilled.
  - What will be the **impact on the society as a whole**? In terms of reduction of risk, impacts on human health and env, on jobs creation/loss (rather than on profit loss), impact on global market, …
    - Impact on actors of the **supply chain** – consumers – job security, employment –
    - **All possible effects** directly related to the targeted hazard properties.
  - Justified **timing required** to switch to an alternative

SEA dossier preparation

- **Description of the impacts due to the regulatory measure**
- Authorisation – for example
  - **Economic impacts** – costs or savings to M/I/DU/distributors and consumer in the supply chain when comparing US and NUS – at National, EU, global level)
  - **Social impacts** – all relevant impacts which may affect workers, consumers and general public (e.g. employment, working conditions, education of workers, social security..) at National, EU , global level
  - **Trade, competition** and economic development – market behavior, economic growth, inflation, taxes, number of competitors (EU, global level)
  - **Substitution cost** – to find, develop and implement an alternative
  - **Geographical extent** of market (National, EU, global) - Etc.
- Restriction – for example
  - Difficulty to achieve the requested concentration
  - Additional cost due to process adaptation, loss of specific market , etc….
  - Implementation time – enforcement
  - Etc.

SEA dossier preparation

- **What does it mean concretely**
- Collect all data from applicant(s) and or DU.
  - **About industry affected** – description, supply chain complexity, total turnover and employment for affected companies.
  - **Economic meaning of the substance** – value added by end product, cost to DU/End users, market price, loss of function, durability, cost to find new alternative
- Explain in details the assessment of the socio economic impact
  - **Difference between US and NUS** – cost difference with /without potential alternative – cost linked to end-product quality modification – cost of relocalisation of (part of) the production, …
- Focus on the **main impacts** and details them
- but don't forget to consider **wide range of impacts**
  - Wider economic impacts
  - Distributional impact



SEA dossier preparation

- **What does it mean concretely**
  - if remaining risk is very low = > very low exposure to workers but other cost to society (e.g. impact of the excess cancer risk) might be significant

  ⇒ e.g. impact related to **man via the environment.**

  - **=> it is recommended to conduct a sensitivity analysis on those parameters and to refine the assessment.**

- SEA expert will launch the assessment based on **existing SE methodologies**
  - Note that some **challenges** remain on scenarios and methods to be applied to draw conclusion. (how to account for job losses, MvE, ED, …)
- **Recap** the assessment considering data provided in the CSR and AoA

  => **ensure consistency** between data (time frame, number of alt assessed…
- Explain the outcome of the uncertainty analysis
- Estimate whether **B>R** => application for authorisation is still needed?

SEA DOSSIER PREPARATION

- **Link SEA with CSR and AoA - potential outcome**

No alternative available (tech/substance)	• Risk of export of risks and benefits
Suitable alternative available	• Authorisation not granted • Restriction may apply
Alternative exists but not technically feasible	• Implying reduction of performance and consumer surplus losses
Risk of alternative similar or higher	• Regrettable substitution
Alternative exists but economically infeasible	• Meaning higher costs (new installation) and or high variable cost (increased production cost).

SEA dossier preparation

- **By Whom?**
  - Applicant – companies – third parties – authorities
  - BUT with the collaboration of someone having the **expertise**!
  - Experts from business dpt, market, environment, HSE, process, technology, R&D, SEA.

⇒ Iterative approach, need to be understood by all parties developing/assessing the dossier => ensure **COHERENCE**

Restriction

⇒ By MS/ECHA drafting the Annex XV dossier

⇒ Early input from industry is often more than welcomed

Authorisation

⇒ Single application => own company information, own process, narrow scope (better detail), more straightforward

⇒ Joint application => via third party, consortium, broader scope, more assumptions and uncertainties to manage.

SEA dossier preparation

- **When ?**

⇒ **Well in advance** of the submission of the restriction or authorisation dossier (whatever the route chosen – adequate control or socioeconomic route – even if mandatory only for the SEA route).

⇒ Coherence, clear, comprehensible explanation accompanied with robust evidence is key and takes time.

Restriction

⇒ Contact the MS/ECHA responsible to develop the restriction dossier.

⇒ Set up as soon as possible constructive collaboration and share relevant data on time (before or when indicated on the registry of intention)

Authorisation

⇒ Once the substance is on the candidate list, collect data available to you

⇒ Develop your supply chain communication and set up your network

Recommended timeline

My substance has been listed – how to react?

- **Identify the list – status, role, actions required**
  - Issued by the COM (legal action) – by ECHA (recommended or legal action) – by other parties (personal opinion to react)

- **Focus first on ECHA's lists – Registry of intention, restriction or candidate list – prioritization**

RoI – warning to act

- clarify the issue with authorities - restriction/SVHC ID/HCL
- ensure all relevant data are available – RMOA to be developed? What is the best route to tackle the concern?
- prepare input for the upcoming public consultation.

My substance has been listed – how to react?

Annex XV for restriction – recommended to act

- Keep contact with authorities for constructive outcome
- Organise your network and provide input during the public consultation (PC).

SVHC identification – recommended to act

- Organise your network – check available option of risk management measure.
- Provide hazard data but also SEA data during the PC.

My substance has been listed – how to react?

Candidate list – obligation and recommendation to act

- Communication duty along the supply on the presence of SVHC.
- Develop a use map where this SVHC is involved
- Develop your supply chain network – identify actors
- Organise your network and prepare input to feed an RMOA (with SEA impact) and /or the potential next step – prioritisation public consultation (PC).

Prioritisation – recommended to act

- Network organized – define critical uses, actors, available relevant data - define the structure of the organization to prepare afa
- Gather data from your company and from others on exposure (evidence based on HSE review), on alternative and Socio economic impact.
- Provide evidence and available assessment during the PC.

Authorisation – recommended timeline

Annex XIV – LAD and Sunset Date – obligation to act

- **Obligation to phase out** after the SSD if no afa granted
- Decided to apply?
- **Develop an authorisation strategy** – who is impacted, who may apply to ensure my concerns are covered.
  - upstream, downstream actors, end users applications?
- Set up an **organizational structure** (resources, task force, consortia, etc.. If needed) – define the aim – the scope – single or joint application?
- **Sensitivity assessment and launch of afa data collection** – URGENT – define a timeline process to gather information
- Biggest effort on time/resources should start first to allow an iteration of the application to achieve a high quality AfA.
  - Exposure data – Alternative data – R&D

Authorisation – recommended timeline

Annex XIV – LAD and Sunset Date – obligation to act

- **Iteration period** assess all available data (exposure – SEA – AoA – RMM conditions) – identify gaps and uncertainties
  - Need further time to fill in the gaps/uncertainties

Annex XIV – decided to apply

- **PSIS and submission** – check of coherence of the dossier - SEA, AoA, CSR parts- with ECHA.
  - Need time to potentially refine the dossier and update the AfA
- Submission – final check on the broad information of use
- PC on potential alternative is launched.

=> Timing is function of the scope and the extend of application

=> Single company/single use/ if well organized = around 6 months

Authorisation – recommended timeline

Annex XIV – LAD and Sunset Date – obligation to act

- **Emergency action –** you just realized your substance is on Annex XIV!!!
- Look at broader context – understand the afa process and the supply chain – find resources or join existing group
- Look into your own company
- gather internal available evidence – gather info on your use (OC/RMM in place), monitoring data, exposure data & releases, number of workers, sites, SEA data, AoA – R&D etc

- => according to the use maps, available data and supply chain actors/impacts
- **=> Define whether you still need an authorisation!**

- => if yes define which approach is the most suitable (up-DU-mid stream application).
- Prepare the dossier – BiU clarification - **submission**

General industry recommendations

Industry recommendations

- Consider the structure and advices provided in practical guidance and other available material to develop SEA
- Find adequate expertise – in house - outside
- Be transparent as much as possible
- Pay great attention to the analysis of alternatives before you start!

=> Often the link between AoA and substitution efforts is missing!

Industry recommendations

- Make a scoping study before you start
- Which environmental or economic end-points to cover?
- Technical system boundaries. E.g. upstream/downstream effects?
- Geographical system boundaries
- Consider impact on applicant but also on the whole society
- Start your preparation as early as possible considering the value chain and make sure the required data are gathered!

=> communication strategy

Industry recommendations

- Verify that your baseline is correct
- Don’t be afraid to quantify where it makes sense
- Do not over-/underestimate the impacts for strategic and non-strategic reasons, e.g. impacts on competitors
- Time scale issues
  - Moving reference situation
  - Discounting
- Uncertainties
  - What do we know? What do we know that we do not know? What do we not know?
  - How to analyse and present what we know and what we do not know?

Industry recommendations

- Stepwise – iterative procedure
  - Less uncertainties for ‘straightforward cases’
  - Proportionality
  - Balanced SEA based on CSR and AoA outcome
- Transparent presentation of results (with support document/evidence for traceability), explaining
  - assumptions made,
  - methodology used to assess and compare impacts
  - uncertainties encountered,
  - distributional issues and
  - the overall outcome.

Conclusion

Conclusion

1. Without socio economic analysis, no adequate policy measures could be taken.
2. Analysis of alternatives provides information on what will happen if an authorisation is not granted (C/B for the primary affected actors) – SEA will assess whether that is better for society or not. (C/B for society as a whole)
3. Very important to present the case and data in a comprehensive manner – clear application (including uncertainties) = clear assessment.
4. For restriction or Authorisation – don't wait to start collecting data to ensure right input will be given at the right time.

THANK YOU for your attention

GRAZIE per la vostra attenzione

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Question

What is the added value to develop a comprehensive – well documented SEA?