Challenges for industry in making an application for authorisation

Hugo Waeterschoot,
Eurometaux

Content

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- Preparing for **Authorisation Applications**
- Safe Use demonstration, SEA, AoA, Substitution Plan
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Authorisation

The way to Authorisation is often seen as :

But is this always so?

Do we understand how it works?

Do we know how to best prepare for it?

A new territory for all
Experience building

- **Authorisation Applications** are a unique event for industry and experience is presently “close to nil”

- **ECHA support** on AA case building is foreseen:
  - ✓ Early briefings of potential Applicants (Oct. 2012 workshop)
  - ✓ Discussion/Guidance on Broad Information of Use (BiU)
  - ✓ Suggested “conference call/meeting” with potential applicants

DON’T MISS THESE INFO & EXCHANGE MOMENTS…

A new territory for all:
Experience within industry is limited so far

So what are the challenges to deal with?

- How **to be organised** for (common) aspects related to AA?
- Carefully assessing the appropriate "***application route***"
- ***SEA experience*** for AA is (very) limited and first opinions received from consultants are often not consistent
- Extent and level of the ***Assessment of Alternatives***
- ***What "endpoints"*** should be compared for the SEA route (eg only CMR or PBT)
- ...

Preparing for applications

3 key decisions to be made!

- Which **use applications** to submit for and how to describe them ?
- Which parts can be **commonly prepared** and which can not?
- Which **application route** will I choose?

Preparing for use(s) applications

Which uses to apply for and how to describe them?

Questions that can help:

- Are alternatives “readily available”?
- Do they provide the “same functionality”?
- Are they economically feasible?
- Are the hazards/risks for the alternatives lower?
- Are they sustainable in the longer end?

Your answers on some of these questions may be different from your colleagues/competitors!

Preparing for applications

From the start…. **DEFINE your BROAD Information / Description of USES carefully**, considering:

- Need for detail on Technical Specifications
- Balance with CBI
- Can a relevant Impact Assessment be performed

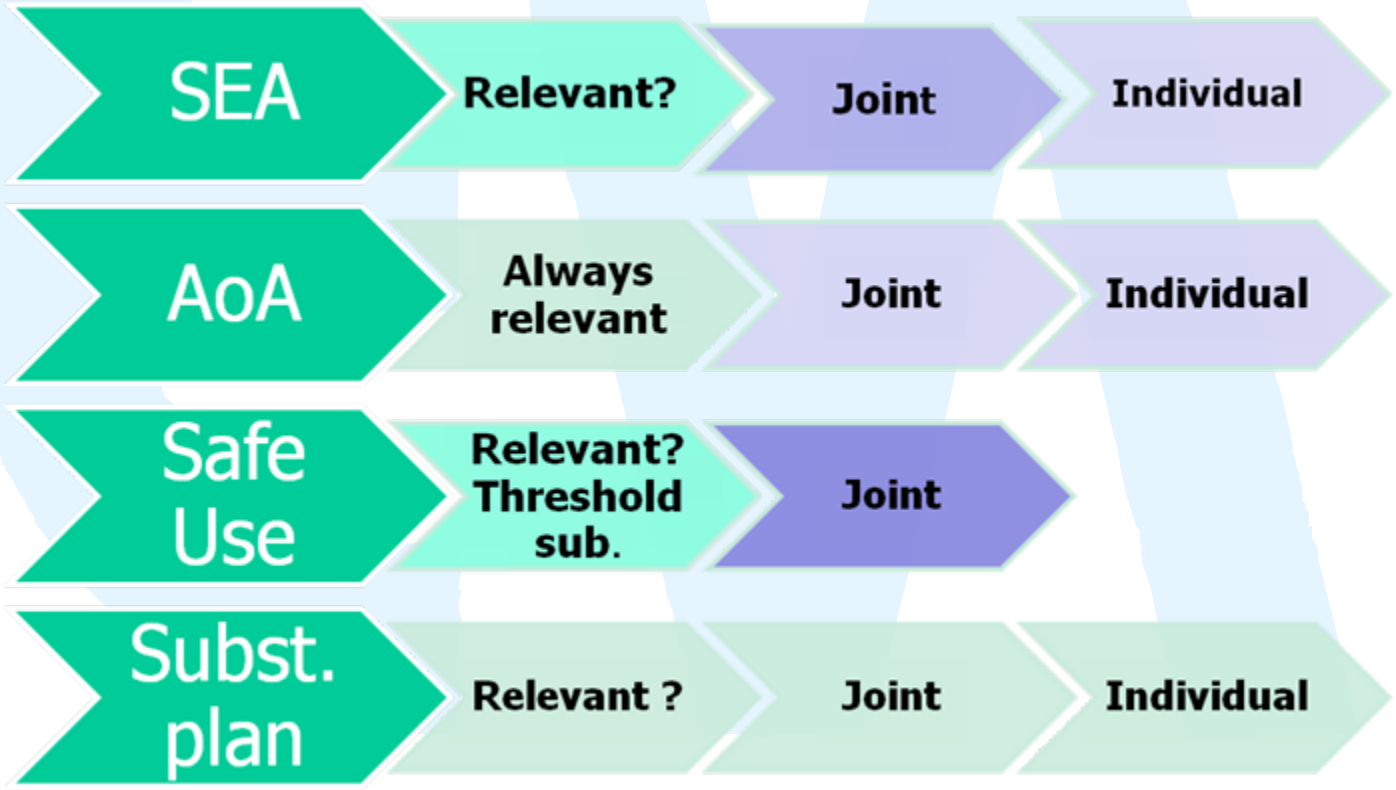
Example: for a battery constituent!

- *Battery constituent to charge rechargeable batteries* ***OR***
- *Battery constituent to charge high density automotive starter batteries allowing cold start*

Preparing for applications

Which parts can be **commonly prepared and which can not?**

Needs:



It is essentially **YOUR CHOICE** !!!!

Joint applications

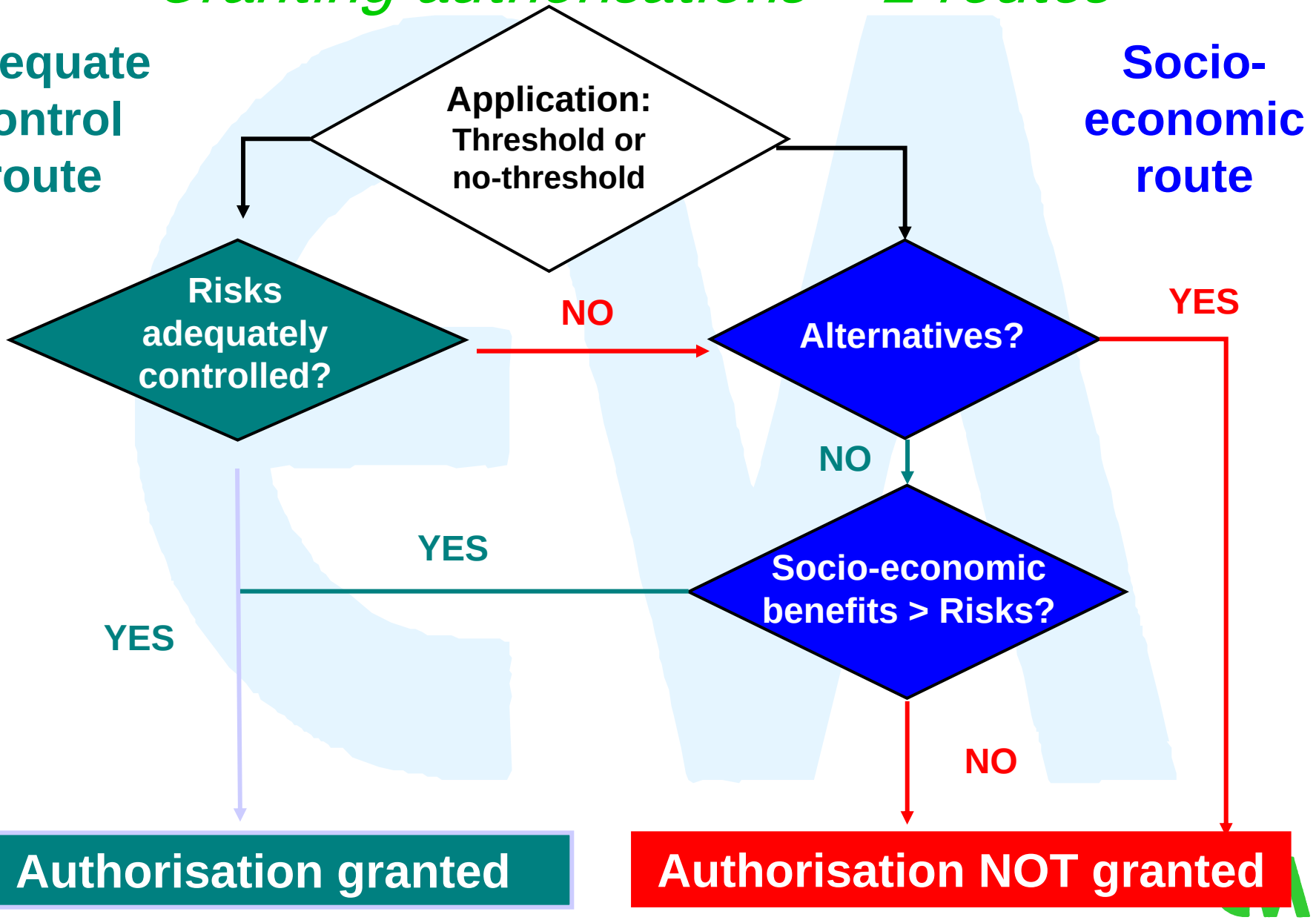
"X" means relevant, "O" not relevant

Com -pany	Use A	Use B	Use C	Use D	Use E (CONF.)
1	X SP : InSEA : Joint Safe Use : Joint Reg : Joint	X SEA: Joint SP: Joint Safe Use : Joint Reg : Joint	X SEA: Ind SP : Ind Safe Use : Joint Reg : joint	X SEA: Ind SP : Ind Safe Use : Joint Reg : joint	X SEA: Ind SP : Ind Safe Use : Ind Reg : Ind
2	X SEA : Joint SP : Ind Safe Use : Joint Reg : Joint	X SEA: Joint SP: Joint Safe Use : Joint Reg : Joint	O	X SEA: Joint SP : Joint Safe Use : Joint Reg : joint	O
3	X SEA : Joint SP : Ind Safe Use : Joint Reg : Joint	X SEA: Joint SP: Joint Safe Use : Joint Reg : Joint	O	O	O
4	X SEA : Joint SP : Ind Safe Use : Joint Reg : Joint	X SEA: Joint SP: Joint Safe Use : Joint Reg : Joint	O	X SEA: Joint SP : Joint Safe Use : Joint Reg : joint	O

In this example: All will work together on "A" for SEA and RA but not for SP. While for use "B" all would like to work together on all aspects. On "use D", company 2 and 4 will work together. All other uses will be individually prepared.

Choosing the right Application Route

Granting authorisations – 2 routes



“Adequate control” vs “SEA” route

- **Decision criterion**: Threshold or non-threshold substance
- **Clear choice** relevant for:
  - ✓ **Preparatory activity** by industry (“scientific evidence” versus mainly “economic”)
  - ✓ Level of detail and focus for **SEA**
    - × SEA route: obligatory
    - × Safe use route: valuable e.g. for defining review period
  - ✓ **Assessment of Alternatives**
    - × Focus on CMR endpoints
    - × Comparing all relevant tox/ecotox endpoints
  - ✓ **Substitution planning**
  - ✓ Proposing relevant **review dates**

The applicant makes the choice based on “scientific evidence”
BUT: ECHA-RAC can eventually contest this

SEA, AoA, Safe Use demonstration and Substitution planning

In order to be well prepared **industry NEEDS CLARITY** on:

SEA :

- What are the recommended assessment parameters?
- Quantitative or Qualitative comparison
- …

AoA :

- What level of detail?
- Including the hazard profiles of the substituents for all endpoints?
- …

Safe Use demonstration :

- What endpoints to consider ?
- …

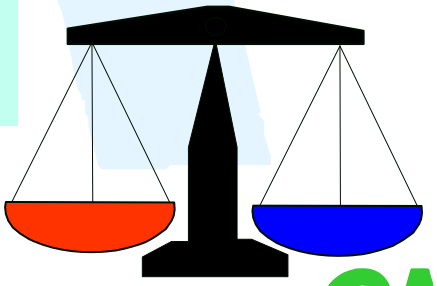
Further clarifications on ECHA on some of these points are welcomed.

Assessing Suitability of Alternatives under REACH: *Technical & Economic Feasibility*

- **REACH and SEA guideline** requires SEAC to consider the ECONOMIC & FEASIBILITY of SUBSTITUTES.
- **Technical feasibility** of an alternative is determined by the alternative fulfilling or replacing the ***function***
- **Economic feasibility** is not a standard economic concept and should ideally assessed through investigation of costs and benefits.

  Whose costs and benefits: Industry, individuals, society?

Technical and Economic feasibility can therefore **differ between companies and certainly between uses** !!!



When to start and to submit…

Just some experience:

- Collecting data and iterative AoA assessment together with DU's: 1 y
- Collecting data on SEA assessment: 1,5 y
- Updating the Safe Use assessment: 0,5 y
- Substitution planning: ? (to company specific)

STARTING Application preparation at the time of publication of Annex XIV entry is **ALMOST TOO LATE**!!

When to start and when to submit?

ECHA defined "*Windows of best Application Periods*"

Idea: best timing for Applicant and ECHA (RAC-SEAC)

When:

- 18 May - 1 June 2012
- 20 August - 3 September 2012
- 19 November - 3 December 2012 (musk xylene, MDA)
- 15 February - 1 March 2013
- 20 May - 3 June 2013 (DEHP, BBP, DBP and DIBP)
- 19 August - 2 September 2013 (diarsenic trioxide, diarsenic pentaoxide, lead chromate, C.I. pigment yellow 34, C.I. pigment red 104)
- 18 November - 2 December 2013 (HBCDD, TCEP, 2,4-Dinitrotoluene)

Don’t forget the review date?

Authorisation applications are temporal and need re-application before the review date!!!

Info that can be most useful for ECHA-Com and the Commission to determine a review date:

- ✓ Technical complexity of the substitution (safety standards, Technical specifications, …)
- ✓ Other sustainability aspects
- ✓ Risk for replacing “manufacturing” by “import”
- ✓ …

So… provide adequate info and proof in SEA, AoA, SP, … During the first application request!!!

Some first experiences

- Willingness to ***share experience*** on AA related aspects (administratively, SEA, ...) but not on AoA...
- ***DU's are*** often more ***engaged*** to prepare and submit an AA than manufacturers:
  - ✓ Often when low value substance or sourcing mainly through import
  - ✓ They have a broader view on relevant alternatives/techniques
- ***Stopping production*** in favour of elimination as hazardous waste
- ***Replacement*** by import of articles
- ...

Conclusions

- **Authorisation applications are new** for all of us!
- Many aspects related to **practices**, SEA, AoA and SP content **are still unclear**
- **Early preparation** and experience gaining is a MUST-MUST-MUST-MUST-MUST-MUST....
- ECHA is invited **clarify outstanding aspects**
- **Collaboration between applicants** is feasible but a flexible attitude will be required
- Industry has to submit **solid and comprehensive dossier**

Like **an Apollo rocket an application** is risky and better very well prepared because there is no return once launched

Hoping I have provided you with an insight on the challenges of industry

Thank you.