Joint versus Individual applications and Downstrean User Considerations

Hugo Waeterschoot,
Eurometaux

Content

- AA **new territorry** for all
- Preparing for **Authorisation Applications**
- **Joint** applications?
- Specific **DU concerns**
- **When** to start and submit?
- Conclusions

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

Key decisions to be made (amongst others !)

- Which **application route** to choose?
- Which **use applications** to submit for and how to describe them ?
- Can parts be **commonly prepared** or not?

Will review each of these issues from:
-Different consequences for the ***Downstream User***
-"Joint" versus "individual" Authorisation applications

Preparing for use(s) applications

Which uses to apply for and how to describe them?

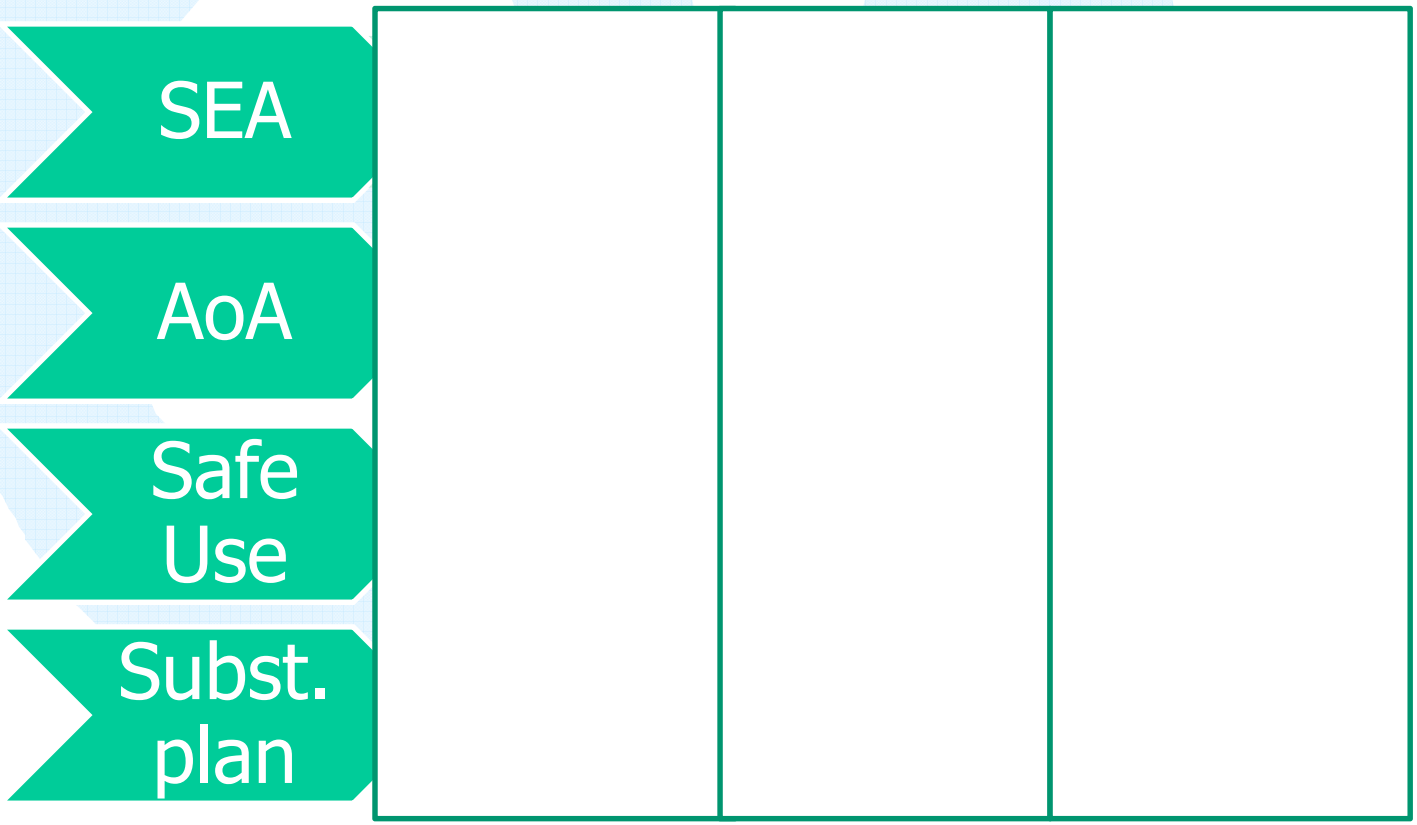
Questions that can help:

- 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 or all of these questions may be different from your colleagues/competitors!**

Preparing for applications

- Which parts can be **commonly prepared and which 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.

Joint versus Individual applications

+ Joint	+ Individual
☞ Issues of common concern (DNEL-CSR-...)	☞ Issues of company specific concern (SEA-...)
☞ Collaboration by use (sub)application at DU level	☞ Different use coverage between manufacturers
☞ Drivers for Cost-Impact-Substitution	☞ Company specific data sets
☞ ...	☞ ...

"Joint" versus "Individual"

Whatever option you choose :

BE CLEAR what is COMMON
and what INDIVIDUAL

and try to handle it in a **STRUCTURAL WAY**:

- parts common
- eg SEA's separately

"Joint" versus "Individual"

Experience :

- Higher tendency for Joint Applications at ***DU level by use***
- Lower tendency for Joint Applications between ***manufacturers with different use patterns***

Specific DU issues:

- Organisational aspects (Consortia, Scope, ...)
- **Access** to CSR-DNEL's-...
- Who would submit for application?

DU issues

DATA access: CSR is required :

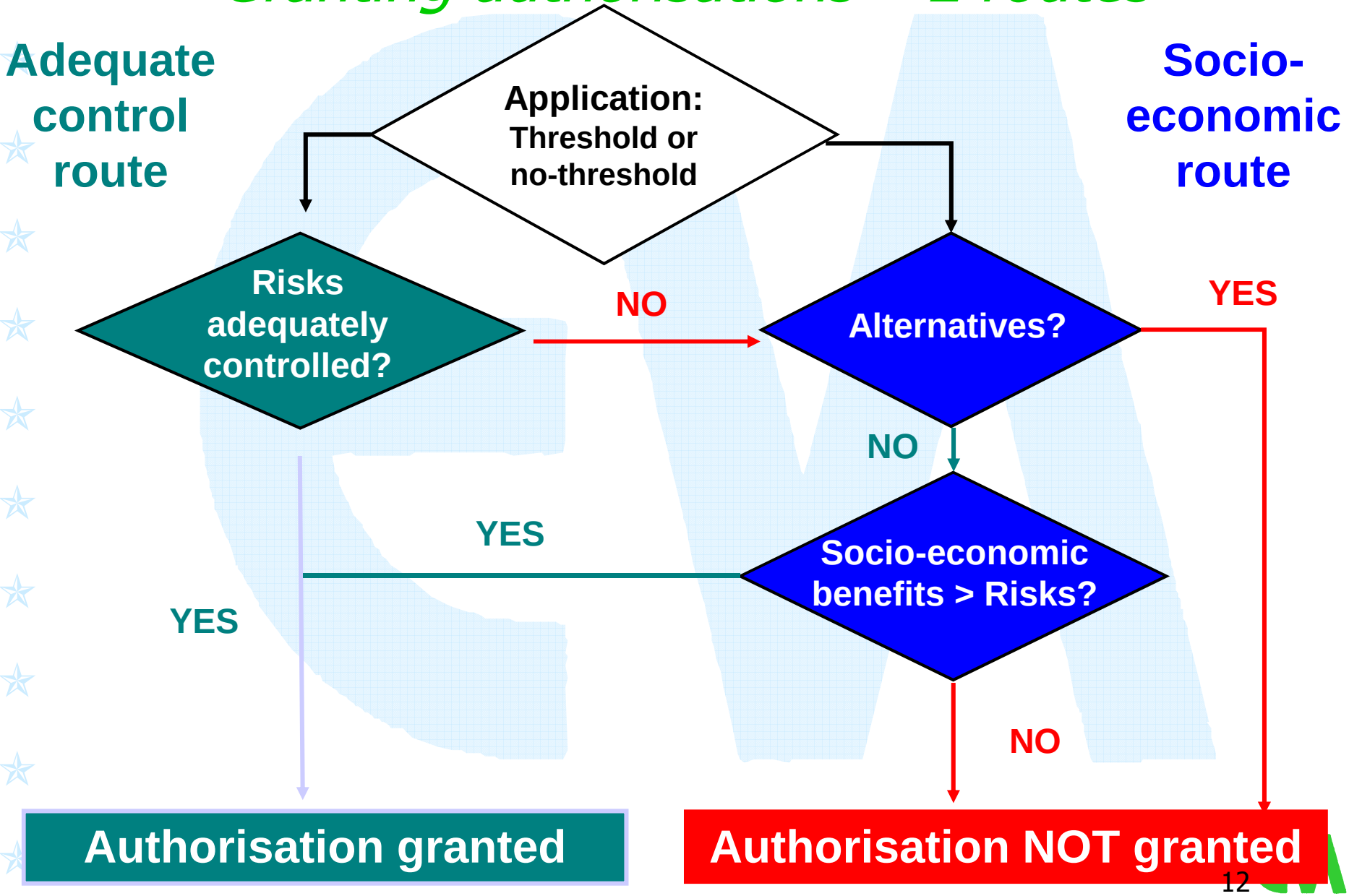
BUT can be restricted to "endpoints of concern"

ALTHOUGH : makes comparison with potential substitutes difficult

RECOMMENDATION: consider data access for all relevant hazard endpoints to ensure fair comparison with potential alternatives

Choosing the right Application Route

Granting authorisations – 2 routes



DU issues

- Level of cooperation will **depend on application route** chosen

Adequate control : joint view on DNEL's

if possible joint view on AC

SEA route : joint view/use on "drivers"

if posisble joint view on SEA and AofA

When to start and when to submit?

In general : 1 y for SEA/AofA + data handling

In case of **DU applicants** : + 6-12 months for organisation

ECHA defined "*Windows of best Application Periods*"

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

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”
- ✓ ...

Conclusions

- **Authorisation applications are new** for all of us!
- **Early preparation** and experience gaining is a MUST-MUST-MUST-MUST-MUST-MUST....
- **Collaboration between applicants** is feasible but needs carefull planning and a flexible attitude
- **AA's at the DU level** are challenging and need time to ensure proper collaboration
- An authorisation application can **grant market access** for a significant period !

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.