Joint versus Individual applications and Downstrean User Considerations

Hugo Waeterschoot, Eurometaux
Erwin Annys /Amaya Jánosi, Cefic

Content

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

A new territory for all:

Experience within industry is limited

BUT increasing fastly

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 SEA assessments from consultants are sometimes too broad in scope and not always consistent
- The "extend and level" of the ***Assessment of Alternatives***
- ***What "endpoints"*** should be compared for the SEA route (eg only CMR or PBT)
- ...

cefic

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 term?

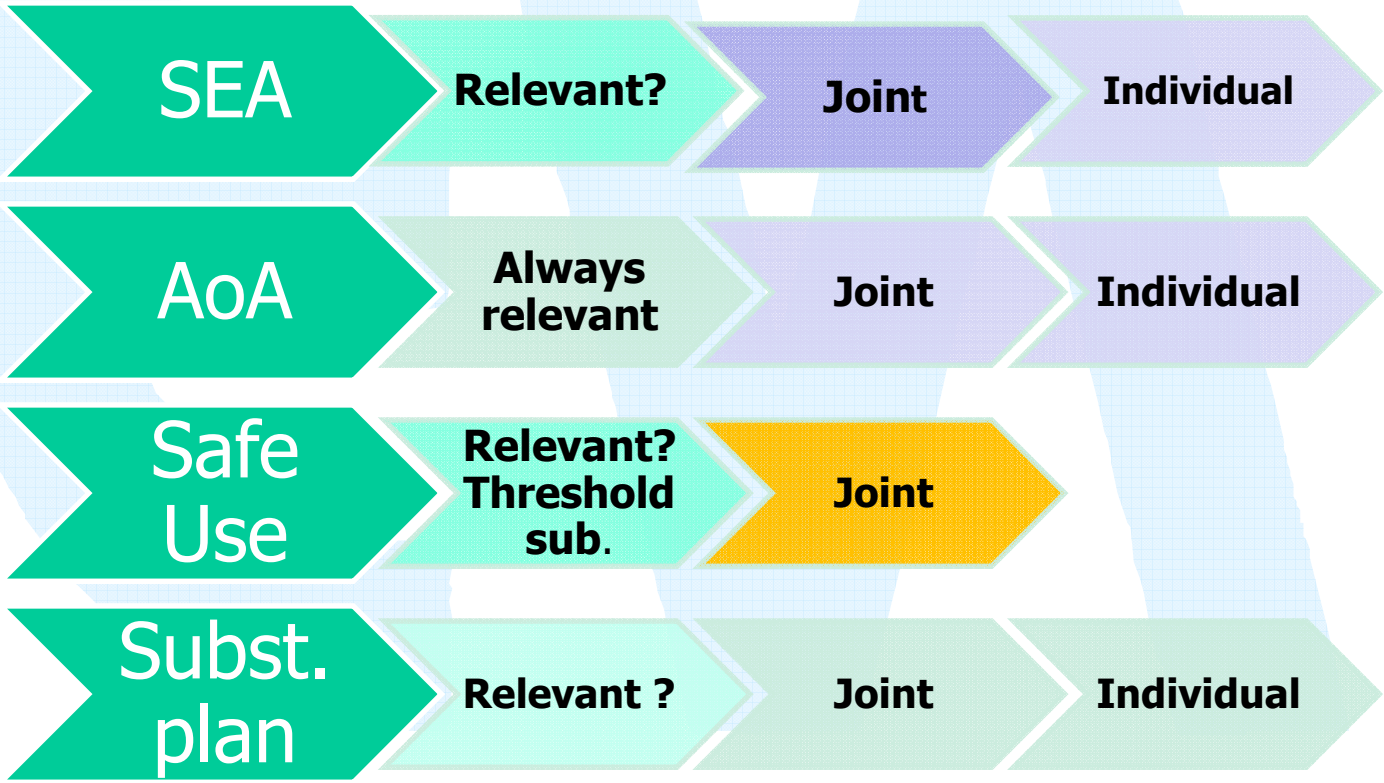
Your answers on **some or all of these questions may be different from your colleagues/competitors!**

cefic

Preparing for applications

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

Needs (e.g.):



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 SEA : Joint SP : Ind 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-...)
☞ ***Common "uses"*** to apply an application for	☞ ***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 is 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 (formulators or users) by (common) use***
  - ***Manufacturers when simple supply chain***
- Lower tendency for Joint Applications between
  - ***manufacturers with different use patterns***
  - ***DU level if specific CBI issues involved***

Issues:

- ***Organisational*** aspects (Consortia, Scope, ...)
- ***Access*** to CSR-DNEL's-...
- ***Who would submit*** for application, the DU, formulator or the Manufacturer

DU issues

DATA access: CSR is required :

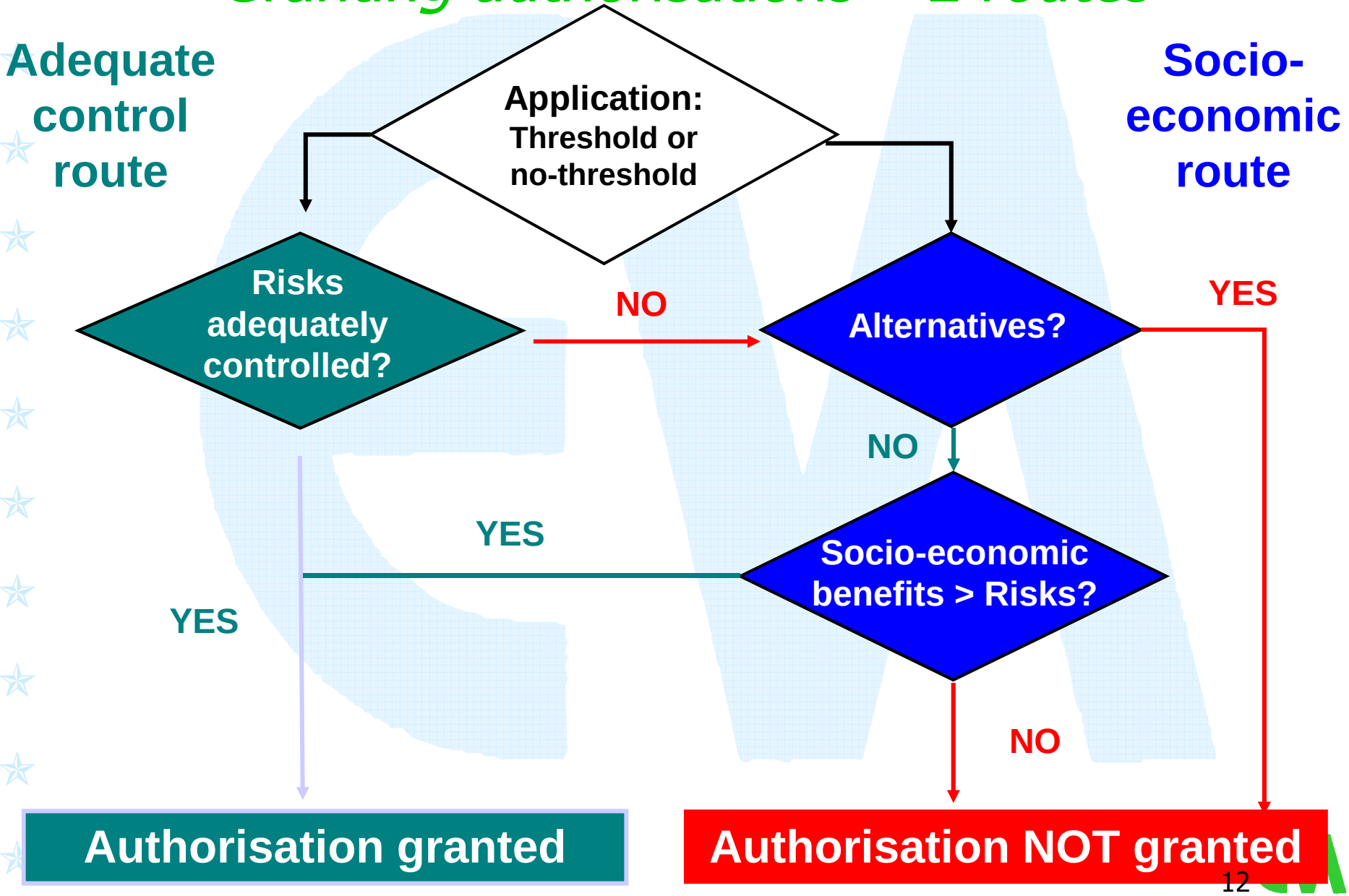
BUT can be restricted to "endpoints of concern".
Reduced need when accepting ECHA-RAC DNEL/DMEL proposal

ALTHOUGH: focus on one endpoint makes comparison with potential substitutes difficult

RECOMMENDATION: consider data access for 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** chosen
- **application route**

Adequate control : joint view on DNEL's

if possible joint view on AC

SEA route : joint view/use on "drivers"

if possible joint view on SEA and AofA

At what level to submit ?

Authorisation is only valid for a "use & one step up" !

- ***LEVEL 1***: Submission by manufacturer/importer:
  - Not legally required but "practical" in case supply chain needs are clear and transparent
- ***LEVEL 2:*** Submission by formulators
  - Required when different step as manufacturer/importer and L1 does not submit an AA !
  - May in parallel (with L1) submit to keep all options open
- ***LEVEL 3:*** Submission by (end)-user
  - Required when importing ex-EU !
  - May in parallel (with L1-L2) submit to keep all options open

Submission is more than a **financial/technical issue**.
Consider **strategic options** too !

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)

CONSIDER:

- submiting JOINTLY / USE as "individuals", to facilitate "common assessment"

Don’t forget the review date (1) !

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

Additional info that can be most useful for SEAC 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”
- ✓ ...

Don't forget the review date (2) !

Principles:

- "***Normal***" (7y), "***Short***" (3-4,…) & "***Long***" (12), ***Longer*** (>12)
- Flexibility on a "***case by case basis***" (e.g. other legislation (RoHS), …)

"**Short**" if :

- AofA is not credible in demonstrating that there are no suitable alternatives.
- Significant technical or scientific uncertainty related to the impacts of authorisation.
- The applicant is seeking 'temporary' (short) authorisation enabling transition to an alternative

"**Long**" if :

- Investment cycle is very long
- The costs of the using the alternatives are very high and very unlikely to change (no technical progress to be demonstrated)

Conclusions

- **Authorisation applications are new** !
- **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. Common preparation is an option while submission can be separate
- Carefully consider the **submission level**
- **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 but requires good justification.

Like **a rocket an application** is best very well prepared because there is no return once launched