

Authorisation: « Classical myths » that require clarification

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Myth 1



« Entering the Candidate List is the first step in banning the substance! »

- Not all substances on the candidate list are selected for Authorisation.
- Annually some are selected and prioritised based on criteria
- Some downstream users may use it like this
- See the candidate list NOT as a banning list but « as a stimulus for innovation »



« We need to have an alternative to be granted an authorisation! »

- The non-availability of an technically feasible alternative will facilitate to get an authorisation granted
 - If you really do not have an alternative would facilitate the analysis of alternatives is rather easy
- The non-availability need to be proven in an AofA !
 - Proving the negative is key !
- An upcoming/lack of a feasible alternative will influence the *review time* of an authorisation



« ECHA is responsible for granting authorisations! »

- No, the Commission grants authorisations
 - With Member States (Comitology)
- ECHA Committees (RAC and SEAC) give opinions:
 - Consist of experts nominated by the Member States and appointed by the ECHA Management Board
 - Independent in performing the tasks



« The authorisation process is unpredictable, including the final decision! »

- Every « *evaluation* » is somewhat uncertain !
- Knowing the rules of the game helps reducing this risk
- Attention likely to be paid to key elements:
 - Remaining risks, if granted (from CSR and AoA)
 - Economic and technical feasibility and research initiatives
 - Benefits, if granted (from AofA, and to an extent from SEA)
 - Costs if the authorisation is « not granted » and you need to « use » the alternatives





Myth 5



« The bigger my dossier is, the more chance I have to obtain my authorisation! »

- Almost the contrary !
- The simpler, the more convincing, the clearer so the higher the chance that my points will be recognised
- Don't dilute a strong message with an overload of information
 - Time and costs to implement new materials recognising safety certification
- You are on the right track, if the consequences of not granting the authorisation clearly have negative effects for society



« I need a fully monetised SEA to get my authorisation! »

- What monetisation are you talking about?
 - Of resources costs. Usually possible if prices quantities are known.
 - Of health/environmental risks and related impacts: is difficult.
- If this is your situation, your, case is probably not obvious, i.e. less strong than you think
- A very clear/convincing case may be so evident that it does not need to monetise the « risks » in the SEA
- Don't walk in the bobytrap of a large SEA without proving a lack of an alternative !
- Nothing is more convincing than providing a simple but robust SEA focused on the real driver that makes the difference



« SEA and Analysis of Alternatives (AoA) contain tonnes of CBI!

- The AofA and SEA may indeed contain CBI
 - But is this crucial in demonstrating *why you need an authorisation*?
 - Is CBI info making the difference?
 - and information that is not allowed to be discussed by WTO
- A qualitative or semi-quantitative analysis not revealing CBI may as often be convincing enough to allow clear opinions and a decision



« My manufacturer is not interested to apply so I can't use this substance after the Sunset date »

- Manufacturers (including importers) and Users can apply
- The granted application covers:
 - the downstream supply chain of the applicant for the use covered
 - One step up (as provider of the substance)
- Applying higher in the supply chain for a given use is indeed beneficial for the entire supply chain of a use



« Public Consultation on alternatives or a high risks and can block my granting »

- PC info on technical feasible alternatives may indeed be a « risk »
- ECHA Committees take PC outcome into account !
 - Applicant will be able to discuss this with Rapporteurs and those that submitted the alternative
- This risk can be reduced by:
 - Realistic assessment of technical and economic feasibility
 - a clear and detailed description of the « broad information of uses »
- Relevant alternatives may rather come from Industry than from NGO's



« Joint applications » are cheaper than « separate ones »! »

- You may lose €100,000 to save €10,000
 - Make a clear distinction between the authorisation fee and your own, consultants', coordination etc. costs related to an authorisation
- Series of « specific uses » may be cheaper in the end than covering all uses in one file
- What is the cost of revealing CBI in a joint application?



« Precise description of uses is confidential! »

- Your first impression may be not correct, feeling uncomfortable is not the same as confidential!
- The moment you go for a joint application, your precise use is probably not very confidential
 - If confidential, you should go alone, and your justification may be rather easy
- Uses found even on Wikipedia are generally speaking « not very confidential »



« You cannot apply after the Latest Application Date or after the Sunset Date! »

- You can apply whenever you want
- If you apply after the latest application date, you will:
 - not be allowed to manufacture and use after the Sunset Date and
 - be obliged to stop that activity until you have received the authorisation
- If you apply before before or during the latest application window you may continue these activities until you will have received the decision
 - Even after the Sunset Date





Myth 13



Your turn...

