Authorisation:
« Unauthorised myths »
of Applications for authorisation

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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 »

Myth 2

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

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

Myth 3

« 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

Myth 4

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

- Every « *activity* » is somewhat uncertain !
- Knowing the rules of the game helps reducing this risk
- Attention likely to be paid to key elements:
  - Remaining risks, if authorisation is 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
- No decisions are made in advance (period of authorisation,…)

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 your points will be recognised
- Structure your demonstration
- 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

Myth 6

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

- What monetisation are you talking about?
  - Of resource 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

Myth 7

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

- The AoA and SEA may indeed contain CBI
  - But is this crucial in demonstrating *why you need an authorisation*?
  - Is CBI information 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

Myth 8

« 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 entire 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

Myth 9

« Public Consultation on alternatives or high risks 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

Myth 10

« 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?

Myth 11

« 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 on Wikipedia are generally speaking « not very confidential »

Myth 12

« 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 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…

Support document:

Industry guidance on authorization for DU - guidance co-signed by Cefic , ACEA, ASD, CEPE, Eurofer, Eurometaux, ORO, UEAPME.

http://www.cefic.org/Documents/IndustrySupport/REACH%20Implementation/REACH-Authorisation-Guidance-for-Downstream-Users.pdf

ECHA website

Industry association websites