



Experiences from industry associations Lessons learned from public consultation, trialogue and opinion making

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Workshop Shared experiences on Applications for Authorisation Helsinki – 29 April 2014



Authorisation



- Complex and new procedure
 - « Many unknowns » for all participants in the process
 - Only « one chance » for industry to make a good application
 - Risk of overloading the application
 - Risk of depending from others
 - « Uncertainty » will remain until some authorisations have been granted
 - Different players in the game,
 speaking « different » languages
 - Open minded and constructive approach from ECHA







- Does it bring what was expected?
- Was the expectation realistic?





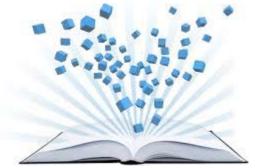


- Major differences between « manufacturers, formulators and downstream users »
 - Alternatives available to the applicant
 - If not available for manufacturers but available for DU, the market will decide
 - Downstream users closer to « product choice » decision





- Potential risk to become:
 - A new marketing tool from companies to promote their substances, not only potential alternatives, but also failures from the past
 - Dating services can be of help?
 - A catalogue of alternatives not fully tested yet
 - How to ensure the quality/relevance check on the proposals?







- « A clearly documented analysis » of alternatives including the alternatives tested and those failed in the use(s) will be very helpful
- « Not tested alternatives » are not feasible now, but reflection needed how to integrate them in future research activities





Trialogue



- « Extremely helpful » in the process if very well prepared by the applicant
- Participants may have « different interests »
- They all « come from planet earth » discussing in « a Babylonian tower »
 - What seems to be clear for industry, is not always clear for authorities and vice versa
- Little time to prepare the answers on the questions, be well organised



Trialogue



- Importance to provide visual support
 - 1 picture tells more than 1000 words
- It is like an examination: be clear, didactic and complete (1 opportunity)
 - Why proposed alternative is (not) suitable –
 functionality specificity quality system, etc...
 - How to proceed with information coming late?
- Closed session foreseen to share detailed confidential information (CSR, prices,...)





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- So far done in a very professional way
- Potential Risks:
 - The trap of the detail is existing
 - The scientific « curiosity » of the Committees may result in only « gold plated » applications that are good enough
- Again, an application that is clear to industry is not always clear to experts



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- Process runs quite smoothly and efficient
- Critical but realistic attitude towards "review times"
- Difficult cases still to come
- How to communicate horizontal learning lessons? (e.g. authorisation and waste)



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- In some discussions, observers could have been useful in explaining some points during the discussion
- Without changing the actual rules, at least the Committee members can ask observers to give a clarification if this need is felt

