Conference on

"Lessons learnt on Applications for Authorisation"

10-11 February 2015

Conclusions

- The Application for Authorisation system works
- It provides pressure on industry to substitute towards safer substances
- It leads to further improvement of RMM
- It is transparent and predictable; companies that can demonstrate a well documented business case will get an authorisation
- But……

Conclusions

- There is room for further improvement
- Costs are on a downward trend but still significant and for some cases the process is too burdensome, possibly even disproportionate
- Nevertheless, even though experience is still limited, dossier drafting may be less complicated than suggested
- The crux is getting the balance right!

Conclusions

- ECHA cares about the applicants, the Committees, the Commission and the process efficiency
- Support, guidance, clarification notes, sharing of good practice etc is generally well appreciated.
- Having DNELs/dose response function is almost a prerequisite
- Need for more specific advice on what a fit-for-purpose dossier looks like
- Committees are prepared and ready to provide further ‘help’ on what they expect to receive

Conclusions

- There are also concerns:
- Have upstream broad applications found the right balance in analysing DU use conditions and possibilities for transferring to alternatives
- Is the ultimate aim of progressively replacing SVHCs with safer alternatives still sufficiently addressed?

Way forward

- Take account of the appreciations, advice and recommendations provided
- Continue improving ECHA's, MSs' and COM's services and support
- Continue trying to simplify formats
- Implement options for general streamlining of the whole process; 'Authorisation right'
- Implement, where justified, asap solutions for special cases; 'Authorisation light'
- Continue to ask feedback from you all