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
• Cost are still high 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 application 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