Conclusions

Streamlining Applications for Authorisation

17 November 2015

Since ‘Lessons Learned’ conference

- Number of applications is increasing
- Application effort and costs have reduced further
- Special cases (low volumes and legacy spares) are being addressed
- Application fee structure to be changed
- We are all still learning
- Substitution can take time, even decades

Reflection

- Agree that applications should be "fit-for-purpose"
  - This may mean different things to each of us
  - Ultimately: to facilitate the work of applicants, ECHA, its committees , third parties, Commission and Member States
  - But keeping up to the objectives of the REACH authorisation: progressive substitution of SVHCs while assuring a proper control of risks

For all applications

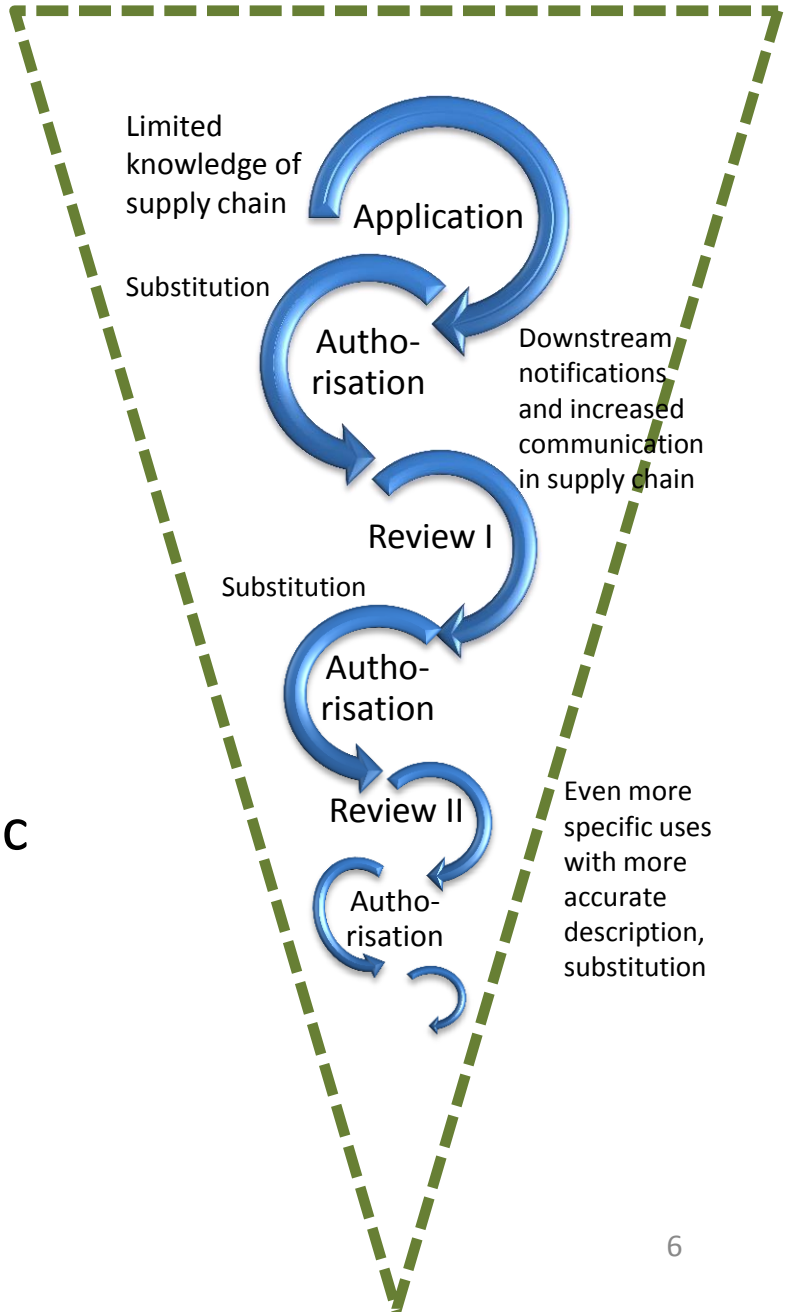
- With right information, applications should cost less and the process be smooth
  - Experience of Committees and Commission decisions helps future applicants to understand what is needed
  - Timely reference dose-response and DNEL are necessary
  - Provide the information transparently (hierarchy of controls for risks, calculations for the SEA…)
- Comparison of monetised human health benefits with risks is not always evident to applicant
- Examples of AoA and SEA are available
- Safer alternatives (in the future) may offer additional benefits

Downstream application

- Good applications are possible to prepare
  - By focusing the effort application costs are reduced
  - Downstream users do not need to supply hazard data
  - Document clearly (including links to supplementary material)
- Preparation of exposure scenarios vs. RAC's expectation was discussed
  - Monitoring data preferred
- Demonstrate "very low" risk and compare with the benefit of authorisation
  - Criteria for "very low" is difficult to get by
  - If "very low risk" demonstrated, could SEA be qualitative?
- Need to have a credible non-use scenario

Upstream applications

- Although not a default, upstream applications are essential to keep the system manageable
- Increased incentive to control the risk or substitute
  - Increased information from downstream users
  - Getting applications more specific and less broad leads to a clearer, understandable and a more transparent process (also easier for 3rd parties to provide input)



Upstream applications

- Get the supply chain involved
  - raise awareness
  - identify each affected actor in a complex supply chain
  - make process and impacts understood
  - receive sufficient information to define scope under which no suitable alternative exist (especially SEA route)
  - maintain trust that authorisation has a chance to be granted
- Narrow use down to where no alternative exists
  - might mean splitting uses if otherwise difficult to describe
- Link the representiveness of exposure data to a specific setting (e.g. technology, scale of operation)
- Non-use scenarios: for dowstream users but also a broader context (your loss may be other's gain)

Follow up

- Commission's implementing acts
  - Low volumes, legacy spares, application fees
- Task Force on the workability of applications for authorisation
  - Need for additional advice / guidelines to build on experience and give practical examples to future applicants (tips & tricks, what is essential and what is not essential, upstream applications)
- Stock taking in 2017