Conclusions

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ECHA's opening

1. Inclusion of substances to the candidate & authorisation lists effectively stimulate substitution and reduce risks in a business friendly, efficient and effective manner
    - 174 SVHC in Candidate list of which 43 in Authorisation list. ECHA adopted 167 opinions on applications
2. Challenges ahead
    - Endocrine disrupting properties for the environment
    - Improve the information in the applications
    - Improve how 'upstream' applications are prepared and managed
        - Downstream user notifications a promising development
    - Review phase of the authorisation system will help, too

Commission's opening

1. Authorisation in REACH intends to address all non-exempted uses of SVHCs that are already on the market.
2. REACH authorisation still is a learning-by-doing exercise, need to live up to that challenge and to get the best out of this unique system
3. Specific DU applications generally have a smooth ride
4. Applications from actors higher up covering multiple DUs is not a default but a possibility: process needs to work properly
5. Faster and more efficient decision making in the Commission relies on good and clear ECHA opinions, which in turn rely on good and comprehensive applications
6. Authorisation is reducing the risks for HH and ENV and improving the risk management measures in the workplace.
7. Authorisation is promoting substitution
    - But also criticism on some parts of the process, including the analysis of alternatives and the public consultation on alternatives

Results of the Commission's study

- "Is authorisation only a burden with no added value?"
  - ➢ No, we see that **it achieves its objectives** in terms of substitution and improvements in the way SVHCs are used (i.e. risk reduction)

- Are the benefits of the **authorisation system** higher than the costs?
  - ➢ It is not possible to answer from the results of the study.
- Interesting findings on the role of the candidate list

Experiences of the applicants

- Single DU AfAs for specific uses have in general a smooth ride (even the 'do it by yourself' ones)
- Large scale upstream AfAs will probably remain necessary but are by nature prone to uncertainties, generally due to the lack of applicants' knowledge of the specific DUs' situations (specific conditions of use and RMMs linked to exposure levels, exact type of products manufactured with the SVHC, substitution possibilities, non-use scenarios). Multi-DU, Hybrid/cluster AfAs seem to be a workable compromise.
- Supply chain communication up and down must improve.
- Scoping the use is of crucial importance in the initial AfAs . Also to define the application strategy (per substance, sector, use), see ECHA new guidance on use descriptions!
- Article 66 DU notifications can help to fill the information gaps and (gradually) narrow down the scope of the use re-applied for during the authorisation period or at the review report stage, e.g. with conditions in the authorisation decision (e.g. refined exposure and alternative assessment and more narrow uses)

How authorisation process has reduced risks

- General agreement between all stakeholders: authorisation process has reduced risks as evidenced
  - by the European Commission study on the impact of authorisation
  - by DU applicants' reporting on the implementation of RMMs during the AfA process
  - by BE enforcement highlighting also the need to strengthen implementation of OSH legislation
  - By RAC in reflecting on the applications scrutinised
- Risk is reduced by:
  - Substitution before and during the authorisation process
  - Implementation of better RMMs and change in OC leading to reduced risk levels either by lower exposure concentrations or less workers being exposed
- Remaining uncertainties being addressed through conditions in the decisions implementing common OSH procedures (monitor, review, improve)
- MS requested to clearly state the reduction in risk achieved, allowing better communication to the policy-makers

Experiences of substitution

- Robust evidence of substitution where authorisation has had a major impact
- Lack of technically feasibility alternatives main barrier for carrying out substitution related work
- Practical examples
  - Arsenic trioxide in Murano glass: Supported by government funded research, tangible and measureable improvement in air quality, next challenge cadmium sulphide
  - HBCDD and DecaBDE in the textile industry: Multiple solutions required, sequential substitution made progress possible, else authorisation is needed, candidate listing initiator
- Alternatives providers: Public consultations starts from the point of view of the applicants? Market for alternatives has developed negatively, no phase-out strategy in the applications
- How can public consultations and trialogues be improved?
- Advantages of collaboration between authorities and industry in finding sustainable alternatives
- Look at options for interaction on alternatives earlier in the authorisation processes (RMOA, CL?)
- Possibility to hold ‘technology briefings’ before applications are prepared?

What has the system cost and what are the benefits

- Commission study provides a partial quantification of authorisation costs of roughly €25 million a year. This comprises:
  - Administration costs for the authorities
  - Costs for applicants to prepare applications and participate in opinion-making (~50 uses p.a.)
  - Costs to applicants for additional RMMs associated with the applications
  - Excludes the costs of substitution, compliance, relocation nor the costs to third parties
- The benefits identified in the study could not be quantified. They include:
  - Human health and environment benefits: Clear evidence of improved RMMs and reduced exposure
  - Benefits of substitution: Mainly reduction in exposure and emissions
  - No clear benefits from closure and relocation: very few cases of relocation or closure identified, relocation moves the risks to outside the EEA
  - Benefits to alternative suppliers: Authorisation process helps to create a market for alternatives in a controlled way
  - Benefits of better information: Improved transparency and communication with authorities

What has the system cost and what are the benefits

- Commission study could not quantify the costs of the whole authorisation system. More information is needed to allow comparison of benefits and costs of the authorisation system.
- ECHA's meta-analysis of applications for authorisation gives some indication about the size of benefits achieved by additional RMMs:
  - Using empirical data from French plating industry, exposure reductions that have been achieved in the chrome plating industry could be about 30%
    - Some caveats exist, but even under different assumptions of the effects exposure reduction of 10-20% could be achieved
  - Additional RMMs and OC for chromates as well as authorisation applications for other SVHC reduce exposures further

Outlook of the years to come (1)

Alternatives and substitution:

- Is the supplier of the substance the right party to do the AoA? How to handle this design flaw?
- Could ECHA better support the work of its committees: using data on substances, uses more extensively?
- Function-oriented substitution needs more specific use information than found in registration dossiers?
- Can the involvement of alternative providers be promoted earlier on (at CL listing), organise more specific supply-chain activities
- Before public consultation: better inform alternative providers on what info they should provide
- Important to ensure that the actual (downstream) users of the substances (and their clients) are involved as they can judge the technical feasibility
- Start as early as possible, e.g. at PACT
- Note though that application dossiers need to contain info on alternatives, also if these are not technically feasible
- ECHA, in the context of the substitution strategy will further develop the supply chain workshop concepts

Outlook of the years to come (2)

Making it more cost-effective:

- More standardised formats, e.g. table-like, examples of good cases
- Build further on the experiences with the practical guide and the use description guide
- Be more clear on the exact expectations from committees and decision-makers
- Provide reference DNELs and dose-response curves as early as possible
- Longer LADs to along better preparation may work but should not stop companies from applying early, e.g. split by use
- Proposal to change the fee structure should help

Outlook of the years to come (3)

How can the supply chain communication improve:

- Strong role to play for the national and EU wide associations to increase awareness. Use as well as article oriented sectors.

- Also a role for national authorities and/or chambers of commerce. Use of national languages is key.

- Get distributors and trade-unions involved as well.

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…… there is room for further improvement!

Conclusions

- Since February 2015, we gained much more experience, have much more facts on the table
- Authorisation achieves its objectives in terms of promoting substitution and risk reduction of SVHCs
- But there's still room for improvement
  - Matching use description and AoA and involving alternative providers
  - Cost-effectiveness of applications
  - Supply-chain communications