# **Closing remarks**

**Seminar on applications for authorisation** 12 April 2011

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## We are all learning

 Authorisation is new for all parties involved; we – potential applicants, third parties, ECHA,... – are entering a "*learning by doing*" phase, in which sharing of experiences will play a key role.

Some aspects of the legal text and how these will be implemented in practice are still unclear: ECHA and the Commission are working to provide clarifications as soon as possible.

#### A well prepared and structured application is vital

- The authorisation application procedure is challenging. It has very tight timelines. Many activities and actors are involved. Every actor will have to seek for efficiency.
- For applicants, the approach and structure followed to develop their applications are crucial to provide ECHA's Committees with a basis for transparent and efficient opinion-making.



#### Applicants need to make strategic choices

- Applicants need to decide on their strategy to develop and submit applications for authorisation. This is likely to be done on a case-bycase basis. In particular, applicants need to consider thoroughly -- and well in advance:
  - which uses to apply for,
  - what route(s) for authorisation they envisage,
  - whether or not to collaborate when developing their application, and
  - whether or not to apply jointly.

## Good communication with downstream users is crucial

• An appropriate communication within supply chains is very important in the development of applications. In particular, the involvement of downstream users -- including article manufacturers -- is crucial to ensure that all life-cycle steps are addressed.



# Start early

- Some parts of an application for authorisation have never been requested before. They require sufficient preparatory time before a complete application can be submitted to ECHA. This is in particular the case for the:
  - Analysis of Alternatives,
  - Substitution Plan and
  - the Socio-economic Analysis.

#### Build on existing knowledge

• Applicants should, however, build on existing information. They may have collected this in the past.

#### Share experiences

• Sharing (even preliminary) experiences would also be very beneficial for those who are totally new in the autorisation process.

# Prepare well for the consultation on "broad information on uses applied for"



- The public consultation on "broad information on uses applied for" will be an important step of the procedure. Here third parties will provide information on possible alternatives.
- It is crucial that it is run in such a way that it provides ECHA's Committees, and ultimately the Commission, with as much as possible the necessary and relevant information to assess the availability of alternatives.
- ECHA will pay a lot of attention to organise this consultation in the most efficient and appropriate manner.

# Consider what is really confidential in the application

- Applicants will have to thoroughly consider what critical information in their applications should not be disclosed by ECHA. This needs to be clearly identified in their dossier.
- ECHA will ensure that confidential information is preserved, whilst ensuring the overall functioning and effectiveness of the authorisation process. The confidentiality of data will have to be justified by the applicant.



# Follow up

- ECHA will consult all stakeholders in the application for authorisation process, including NGOs.
- Industry and ECHA concluded that a follow up seminar on application for authorisation could be helpful
  - either to different groups of companies, or
  - in specific issues.
- ECHA, in consultation with the Commission, will provide further clarifications on practical and procedural aspects of the application for authorisation procedure.
- Notification of possible applications to ECHA is encouraged.
- Additional information available through
  - ECHA's web-page <a href="http://echa.europa.eu/reach/authorisation\_under\_reach\_en.asp">http://echa.europa.eu/reach/authorisation\_under\_reach\_en.asp</a>,
  - National helpdesks,
  - ECHA helpdesk.