

Closing remarks

Seminar on applications for authorisation
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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. Many aspects of the legal text and how these will be implemented in practice are already clear
- ECHA and the Commission are working to provide further clarifications as soon as possible.
- 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

- Applying for an authorisation is a core business decision. Ask yourself first what you would do if the Annex XIV substance can no longer be used in the EU
- Applicants need to decide on their strategy to develop and submit applications for authorisation. This is likely to be done on a case-by-case 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
- A strong case probably means an easier application: the substance clearly adds value and the remaining risks are small

Good communication within and outside your supply chain is crucial: up, down and side!

- 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
- Similar actors outside your supply chain could provide important information and there might be an interest in working jointly on some aspects

Start early

- Some parts of the applications will probably require quite some time to develop, especially:
 - Analysis of Alternatives,
 - Socio-economic Analysis

Build on existing knowledge

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

Do not overcomplicate your application

- E.g. in SEA: the role of monetisation of impacts is probably overplayed, you need to be able to show that 'costs would be high' and 'risks are low'. You can use contextual information and comparisons

Share experiences

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

Prepare well for the consultation on alternatives

- 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, in consultation with the Commission, will provide further clarifications
- Notification of possible applications to ECHA is encouraged
- Additional information available through
 - ECHA's webpages including the Q&As,
 - National helpdesks,
 - ECHA helpdesk
 - Industry associations