Public consultation on applications for authorisation

Webinar

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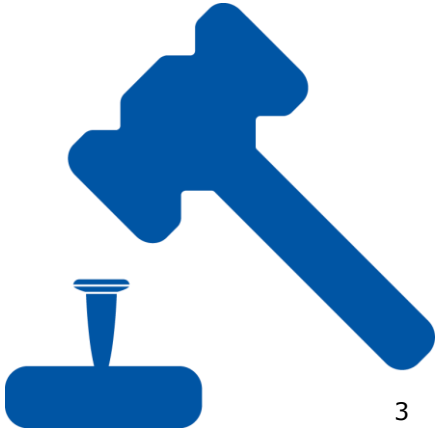
Outline of ECHA's presentation

- Purpose of the consultation
- Who should comment?
- What is in it for me?
- Technicalities (how to comment)
- Experience so far
- Helpful comments
- Less helpful comments
- Examples
- What's next?

Purpose of the consultation

- Information on alternative techniques or substances
  - Technical
  - Economic
  - Availability
  - Hazard and risk
- Consultation needs to be meaningful for the opinion-development



Who should comment?

- Competitors
- Collaborators
- Clients
- Suppliers
- Interested organisations
  - Industry organisations
  - Non-governmental organisations
  - Research institutions

What is in it for me?

- Market opportunities
  - Name and fame
- Improve public health or the environment
- Possibility to provide information on why authorisation is needed
  - For instance, if downstream users see information gaps
- Focused comments
  - Don’t waste your time
  - Don’t waste other’s time

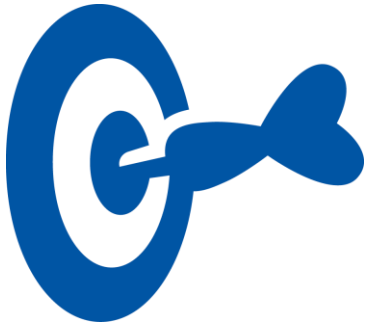
Technicalities

- Eight-week commenting windows
  - 10 February to 6 April (next 11 May to 6 July)
- Entirely web-based system
- Confidentiality
- What to expect
  - All comments are made public on ECHA's website
  - Applicants have the possibility to respond
  - Committees, in particular the rapporteurs, take the comments into account
  - Commentators may be invited to the "Trialogue" about one month later
  - Support: application-authorisation@echa.europa.eu

Experience

- Public consultation held on 68 uses
- 704 public consultation comments received (but not unique – same comment sometimes repeated)
  - In some cases, submitters seem to have been orchestrated by the applicant to gain support for the authorisation
- Applicants always responded
- All on ECHA's website
- Transparency facilitates the public consultation
  - Currently 90-95% of information in applications is publicly available

Helpful comments



- New information about alternatives
  - The more specific, the better
  - Technical, economic, availability and hazard information
- Clear evidence and references
  - Also for additional information
- Understandable information
  - Do not expect that the readers (e.g. in the Committees) understand all technicalities
  - How the information may influence the authorisation, e.g.
    - Not to grant at all
    - Short(er) review period (as alternatives are available soon)
- Possibly corroborate information in the application too

Less helpful comments

- No new information on alternatives
- No comments needed on hazard of substance applied for
  - Substance is known to be hazardous, it is an SVHC
- Usually exposure information is not needed
  - This information should be in the application
- General criticism to grant or not grant the authorisation
  - The purpose of the consultation is to see if there are good alternatives
  - The substance is of very high concern and treated as such in RAC and SEAC

Examples

- Helpful
  - *Experience indicates that the switch to the alternative increases the cost of the final product by 1 - 3%*
  - *Based on publicly available information, the producer of the alternative will increase its production capacity to 10 000 tonnes per year*
  - *Here is additional information on sector-specific end-user requirements that weren't fully outlined in the application*
- Less helpful
  - *Local exhaust ventilation is not used*
  - *The exposure scenario is not sufficiently described*
  - *Please grant the authorisation*

What's next?

- ECHA
  - Hosts this; the next consultation will be even larger
  - Collects feedback on the value added
- Industry and other organisations
  - Get right companies to know about consultations, and their purpose
- Third parties provide comments
- ECHA wants to improve its public consultations
  - Not only in applications for authorisation
  - Perhaps a special session at the next accredited stakeholder organisations' day

Thank you

More information/support:
application-authorisation@echa.europa.eu

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