Authorisation- Experience from NGOs

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Authorisation

Aims that ***SVHC are progressively replaced by suitable alternative substances or technologies***... *To this end* ***all manufacturers, importers and downstream users applying for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution***"

REACH {Art. 55}.

- **MAIN TOOL FOR ELIMINATION/SUBSTITUTION OF SVHC**
- **Authorizations should be an exception.**
- **Only for specific uses and for very limited time.**

Why you should substitute

- **Using/manufacturing SVHC? Houston, we have a problem!**
  - Authorisation procedures for industry are complex, costly and uncertain
  - SVHC are death chemicals
  - High costs of management and control of chemical-related risks

- **Substitution is the main driver for innovation and way out crisis**

- **Substitution is the best way to:**
  - **protect health & environment**
  - To be **ahead of the chemicals legislation**
  - To **meet market demands anticipate market opportunities**

NGOs' role

- **OUR GOAL:** Authorisations are not granted for SVHC for which feasible alternatives are available in the market

- **NGO PARTICIPATING THROUGH:**
  - Public consultations – Information on alternatives
  - Trialogues
  - Observers at RAC/SEAC meetings_ participation limited

Applications for authorisation: NGOs analysis

- **SCOPE:** use specific versus broad: bad quality of the information provided in applications for broad uses
- **EXPOSURE:** better information from downstream user applications needed, exposure not sufficiently and correctly described, risk not adequately estimated, mixture toxicity disregarded as well as other toxicological endpoints.
- **ANALYSIS OF ALTERNATIVES:** in general incomplete, no methodology is followed and substitution plans are lacking
- **SOCIOECONOMIC ANALYSIS:** very poor information: difficult for SEAC to deliver a meaningful opinion.
- **REVIEW PERIODS** not properly justified

ACCESS TO INFORMATION

- **LIMITED due to confidentiality claims by applicants.**

Why is this information important for 3rd parties?

- ✓ Help to define/understand the problem -> support authorisation
- ✓ better understanding on the conditions of use of the SVHC
- ✓ better assess use by & feasibility of the alternatives for the applicant

What are NGOs doing: ATD requests

Is industry winning anything with this?

- ✓ RAC/SEAC opinions development is more difficult
- ✓ ATD high workload for both, the applicant and ECHA
- ✓ Legal costs
- ✓ Distrust, reputation, image, market?

ECHA's role

- **AUTHORIZATION PROCEDURE: narrow/ bureaucratic view:** DNEL for non threshold substances, risks from other properties of the SVHC not considered, etc...
- **Applications accepted before RAC's conformity checks**
- **Hindering 3rd party participation** (acceptance of confidentiality claims and restrictions to speak)
- **Role of ECHA? To facilitate authorization or substitution of SVHC?**
- **Could ECHA do more: all alternatives gathered** by 3rd parties, **substitution** and SE **costs/benefits** in the process

Conclusions

- NGOs want EU chemicals industry to be a frontrunner world wide on sustainable innovation
- Downstream users play a key role - improve communication!
- Clear, comprehensive & transparent PC is key for 3rd parties' contribution & understanding the problem - Alternatives info is not a threat but an opportunity
- ECHA must ensure ALL information on alternatives is gathered in the process and support companies towards substitution
- Hazardous and obsolete chemistry has no future-better substitute asap!

Thank you for your attention!

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