



Stakeholder feedback of the application process

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Authorisation under REACH



Aims that *SVHC are progressively replaced by suitable alternative substances or technologies...*

REACH {Art. 55}.

- **MAIN TOOL FOR ELIMINATION/SUBSTITUTION OF SVHC**
- **Incentive for developing and using safer alternatives**
- **Authorisations should be an exception**
- **If granted: only for specific uses and for very limited time**

Is authorisation delivering? YES!



Applications not submitted for half of the substances included in Annex XIV with application deadline expired

Public consultations, have provided new information on alternatives not considered by applicants and showing the technical & economic feasibility of safer alternatives in the supply chain.

Substitution advancing for specific uses applied for

Improvements on risk management as a result of authorisation process: Applicants implementing RMM after deciding to submit applications. E.g. TCE (textiles) and As_2O_3 (ammonia).

Applications for authorisation



Insufficient information provided by applicants

- **Insufficient information on exposure:** not all uses covered (broad use), mainly estimations.
- **Alternatives:** not use-specific AoA (broad use), mainly drop-in chemical substitutes, not covering DU uses applied for, poor AoA (just CLH info), assessment of costs of alternatives exaggerated, substitution plans are lacking.
- **Socio-economic analyses:** Limited information on benefits/costs for society, external costs not included

Applications for authorisation



SVHC	N° uses and scope
DEHP	4 broad (PVC) + 2 specific
DBP	5 specific
Diarsenic trioxide	5 specific
Pigment yellow	6 broad
Pigment red	6 broad
HBCDD	2 broad
Trichloroethylene	5 broad + 12 specific

Chemical manufacturers applying for downstream users! DEHP, pigments, HBCDD, ...TCE

Our concerns with the process



ECHA has substantially made progress on:

- **Participation:** stakeholders will have speaking rights (general)
- **Promoting substitution** (website, webinars, newsletter...)
- **Transparency:** Public consultation template revisions

But, still needs to improve on:

- **Adequate advice on substitution** (pre-submission meetings)
- **Conformity of applications**
- **Evaluation of confidentiality requests**
- **Participation:** full speaking rights, more frontrunners engaged in the process

Concerns regarding the Committee's opinions



- **No consistency among opinions** (e.g. economic feasibility)
- **Short review period instead of negative opinions**
 - **RAC:** low quality data for opinion development, combined exposure disregarded (DEHP/DBP), EDC mediated properties
 - **SEAC:** feasibility of alternatives; any increased cost means not feasible. Poor consideration of social and frontrunners impacts.

Are RAC and SEAC doing their job?



Assess if applicant demonstrates:

- adequate control
- alternatives are not available/feasible
- SE benefits outweigh the risk to health or the environment

Or doing applicants' work?

- Request info after the applications deemed complete
- Carrying out own assessments/calculations (e.g. DEHP in PVC)
- Viewpoint of the applicant rather than a "neutral" judge for society (including the alternatives users/producers)
- Reference DNEL

Some provocative questions...



- Are ECHA & COM demonstrating REACH works by ensuring applicants get authorisation?
- How can we ensure that the authorisation process is really an incentive for substitution?
- How can we join forces to show the invisible substitutions taking place in the market?
- Are the standards for technical and economic feasibility consistent?

NGOs recommendations to ECHA



- **Allocate the burden of proof on applicants for authorisation**
- **Applications with broad uses or insufficient data are not acceptable and should be rejected**
- **Need to define “economic feasibility” beyond ‘not more expensive’**
- **Better balance between costs for the applicant and external costs associated with SVHC is needed**

Conclusions



- **Incomplete applications should be rejected to give credibility to the process**
- **SVHC are being authorised for continued use, even when safer alternatives are already widely available**
- **Transition to safer alternatives should be encouraged, while increasing market opportunities for “green” companies and incentives for sustainable innovation**
- **Taking into account only applicant’s point of view is narrow approach (benefits for society, companies producing safer alternatives)**



Thank you for your attention!

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