

Dealing with Authorisation Issues

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Why is authorisation part of REACH

- “...Free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation” (“Recital” 1)
- Preservation of “the integrity of the internal market” (“Recital” 7)
- **“High level of protection of human health and the environment...”** (“Recital” 1)

Why is authorisation part of REACH

- “High level of protection of human health and the environment...” (“Recital” 1)
 - ❖ Burden of proof that a substance is safe on the supplier
 - ❖ No longer assumed that a substance is safe
 - ❖ Guilty until proven innocent?
 - ❖ Anything regulators deem dubious may be reviewed
 - ❖ Input from
 - Industry
 - Member States
 - NGOs

Authorisation vs. restriction: what's the difference?

- Authorisation:
 - ❖ May only be used for prescribed applications
 - ❖ Annex XIV list
- Restriction:
 - ❖ May be used except for prescribed applications
 - ❖ Annex XVII list
- Similar processes; different end product
- SVHCs are substances under review, not substances under authorisation/restriction

What are the criteria for inclusion in the authorisation/restriction process?

- CMRs
- Respiratory sensitisers
- PBTs vPvBs
- “Other effects”
 - ❖ Clause 57f catches endocrine modulators
 - ❖ And others?
- Likely outcome?
 - ❖ Severe restrictions
 - ❖ Substitution
 - ❖ Limited lifespan if allowed at all

A SEA of problems?

- What's a SEA?
 - ❖ Socio-economic analysis
 - ❖ A justification for allowing continued manufacture/importation of a substance that meets the criteria for authorisation or restriction
- How does it work?
 - ❖ List of considerations

A SEA of problems?

- A SEA may include the following elements:
 - ❖ impact of a granted or refused authorisation on the applicant(s)/industry (manufacturers and importers).
 - impact on all other actors in the supply chain, downstream users and associated businesses
 - commercial consequences
 - research and development/innovation
 - one-off and operating costs

A SEA of problems?

- ❖ impacts on consumers.
 - product prices
 - changes in composition or quality or performance of products
 - availability of products
 - consumer choice
 - effects on human health and the environment to the extent that these affect consumers

A SEA of problems?

- ❖ social implications
 - job security and employment,
- ❖ availability, suitability, and technical feasibility of alternative substances
- ❖ wider implications on trade, competition and economic development
- ❖ proposals for other regulatory or non-regulatory measures that could meet the aim of the proposed restriction

Moving forward – the key issues

- If it's not listed on the ECHA website it isn't yet under review
- Some substances are in the “political” agenda – especially EDs
- Even when it's listed, its only under review, not on the Annex (XIV or XVII)
 - ❖ Can have input to review process
 - ❖ Need good science
 - ❖ NGOs have an agenda; science may be good... or may not!
- Watching brief

