



US Clients
Seminar
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Caleb and REACH

Role as an Only Representative

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Caleb in the Chemical Regulatory Sphere

- Caleb has worked historically in both policy development and implementation areas
- In the chemical regulatory area, implementation has taken on two distinct characters:
 - ❖ **Collective** responses to regulation (e.g. consortia)
 - ❖ **Individual** company support with product registration and on-going support
- The Only Representative role in REACH emerges from a previous requirement under earlier regulation for a Sole Representative

Caleb as Only Representative

- Caleb thought long and hard about taking the role of an Only Representative
- Key areas of distinction from previous work:
 - ❖ **Legal** responsibility for all aspects of compliance
 - ❖ **Long-term** relationships required with clients
 - ❖ **Unique** communication challenges
 - ❖ **Data** storage requirements
 - ❖ **Uncertain** interpretation of new legal text
- Improving levels of communication will be a key theme throughout this event

Caleb's credentials for the task

- A strong reputation with the authorities
- A clear understanding of risk and how to manage it
- A willingness to support overseas clients with the 'impossible' challenge of REACH (someone has to do it!)
- A culture of openness with clients but recognising the need to manage confidentiality
- Business management experience
- Previous experience with SIEF-like operations and the development of dossiers

Caleb's preparations and challenges

Preparations

- Employment only of experienced chemical regulatory staff
- Breadth of experience across a number of sectors
- Knowledge of the whole supply chain including manufacture and downstream use
- Upgrading of IT infrastructure and procedures for new role

Challenges

- Managing uncertain and changing business priorities
- Managing the interaction with SIEFs and Consortia that might have differing priorities
- Gaining sufficient information on downstream usage patterns

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

