

US Clients
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REACH and the EU Endocrine Disruptor Strategy

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Emergence of EU ED Strategy (1)

- Mid/Late 1990s the Commission focused on the definition of the endocrine system
- A key conclusion was that it should include:
 - ❖ Hormonal effects (androgen and estrogen levels)
 - ❖ Thyroid
- Early action was to commission a consultant (BKH) to prepare a list of all substances which had been reported as having such effects
- No focus on quality or 'weight-of-evidence'
- Some substances already controlled on other end-points

Emergence of EU ED Strategy (2)

- The BKH Study revealed 9 industrial chemicals and 3 natural hormones that were not controlled or under risk assessment
- WRc was contracted to review the dossiers for these chemicals (one was resorcinol)
- The Commission has periodically issued 'Staff Working Documents' to update progress (2003 & 2007)
- BKH list was 'enhanced' in 2006 by work of DHI to extend to include low volume chemicals

Challenges of the ED agenda

- No internationally accepted test protocol (OECD) for confirming ED or not
- Industry has always argued the ED is a mechanism not a toxicological end-point
- No legal definition for an ED making it difficult to legislate
- Several Member States keen to see action to curb the use of some suspected EDs
- Compounded by controversies over low dose effects (e.g. bis-phenol A)

REACH and the ED agenda

- Member States wanted to include EDs specifically under Article 57 (with CMRs, PBTs etc.)
- Commission resisted because they could not legally enforce it without definition
- Article 57(f) became a 'catch all' for those substances that Member States considered dangerous
- Inclusion under Article 57(f) requires a Member State (or the Commission) to trigger an Annex XV dossier

Current interactions

- Some concern initially that the ED Strategy list would be transferred directly under Annex XV
- ED Strategy team has heavily resisted this because ED definitional issues span many other Directives
- Some indication that current focus of the Commission continues to be on testing protocols and science
- Should scan the combined BKH/DHI List during substance reviews to alert possible 57(f) issues

Reminder that Article 57(f) text requires that:

Substances – such as those having endocrine disrupting properties or those having persistent, bio-accumulative and toxic properties or very persistent and very bio-accumulative properties, which do not fulfil the criteria of (d) or (e) for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.