

REACH: CURRENT ISSUES FOR US INDUSTRY

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REACH: CURRENT ISSUES FOR US INDUSTRY – BASIC REACH REQUIREMENTS

- Your substances (exported over 1 tonne per year) banned from the EU market unless duly registered or authorised ('no data, no market')
- No data, no market applies not only to chemical substances exported as such but also:
 - ✓ when included in exported preparations;
 - ✓ when incorporated in exported articles (finished products) if the substance is intended to be released during use or is a substance of very high concern ('SVHC')

REACH: CURRENT ISSUES FOR US INDUSTRY – BASIC REACH REQUIREMENTS

- Pre-register existing ('phase-in') substances between June and November 2008 to avoid immediate marketing ban and to benefit from registration transitional periods
- US manufacturers cannot directly register but must choose:
 - ✓ registration by EU importers (requiring passing CBI to competitors); or
 - ✓ appointment of an only representative ('OR')
- In either case, dedicated resources for:
 - ✓ inventory
 - ✓ supply chain management
- Use of OR ≠ no responsibilities for US manufacturers

REACH: CURRENT ISSUES FOR US INDUSTRY – CREATION OF TRADE BARRIERS?

- REACH arguably creates trade barriers because:
 - ✓ discriminates against non-EU manufacturers (Article 2.1 TBT Agreement);
 - ✓ not least restrictive measures to fulfil the legislative objective (Article 2.2 TBT Agreement); and
 - ✓ unnecessarily burdensome, complex and unclear, particularly prejudicing SMEs.

REACH: CURRENT ISSUES FOR US INDUSTRY – DISCRIMINATION AGAINST NEUMs?

- Good news! USTR success in forcing Commission change of policy
- OR registration not required to aggregate export tonnages of all NEUMs it represents for relevant substance
 - ✓ avoids NEUMs being disadvantaged by more data and earlier registration requirements than EU based M/Is of equivalent tonnages
- Eligibility for registration fee reduction for SMEs based on size of each (not aggregated) NEUM represented by OR (Article 12, Regulation (EC) 340/2008)
 - ✓ avoid NEUMs missing fee reductions enjoyed by EU based competitors of equivalent size
- ... But why can't US exporters register directly?
 - ✓ need input from you on how you are disadvantaged compared to EU M/Is
 - ✓ substance for trade barrier arguments
 - ✓ win further concessions?

REACH: CURRENT ISSUES FOR US INDUSTRY – THE SITUATION OF SMEs

- 'Special account should be taken of the potential impact of the Regulation on [SMEs] and the need to avoid any discrimination against them (Recital (8), REACH Regulation)
 - ✓ Merely lip service?
 - ✓ Only substantive concession is fee reduction (Regulation (EC) 340/2008)
- Real SME issue is burden of compiling dossiers and cooperation on data sharing:
 - ✓ Estimated costs at least EUR 100,000 – 200,000 per substance
 - ✓ Dedication of resources required impossible for SMEs?
 - ✓ Significant withdrawal of substances from market (10% according to US Mission in EU)
 - ✓ need 'real life examples' from you – possible SME *de facto* discrimination argument?

REACH: CURRENT ISSUES FOR US INDUSTRY – THE LEAST RESTRICTIVE MEASURE?

- Does REACH require more restrictive measures than necessary to ensure environmental and public safety?
 - ✓ 'hazard based' since obligations not limited to substances which may be harmful when used as intended
- Publication of candidate list of substances for authorisation
 - ✓ Commission defence is that actual decision to authorise or ban is not hazard based (can risks be adequately controlled?)
 - ✓ ... but why candidate list necessary to achieve legislative aim of controlling most dangerous substances or achieving their substitution?
 - ✓ Commission attempt to steer the market

REACH: CURRENT ISSUES FOR US INDUSTRY – UNNECESSARILY COMPLEX, UNCLEAR OR IRRATIONAL

- WTO Technical Barriers to Trade Committee meeting 20 March 2008
 - ✓ several members state that SMEs lack the capacity to comply with REACH due to its complexity
- REACH still being interpreted and understood (by the Commission as well as industry!)
 - ✓ practical consequences not properly thought through
 - ✓ Existing ECHA Guidance substantively revised by new versions
 - ✓ Guidance sorely needed by industry (on pre-registration and articles especially) still awaited
 - ✓ Guidance and Regulation clearly conflict on some points
- Examples of unclear or irrational provisions:
 - ✓ requirement to register reacted form of monomers in polymers - UK court challenge
 - ✓ biocides co-formulants subject to registration despite pre-existing dedicated EU biocides legislation

REACH: CURRENT ISSUES FOR US INDUSTRY – NEXT STEPS

- US industry should use fact that REACH still being interpreted to its advantage
 - ✓ USTR success to date regarding NEUM discrimination can be repeated
- Need for a forum for NEUMs (including SMEs) to input empirical information to substantiate trade law arguments and exert pressure on Commission
 - ✓ Steptoe & Johnson LLP clearing house for submission of information to USTR
- Act now before US legislation follows REACH model!