

A close-up photograph of a microscope's objective lenses and eyepiece, rendered in a blue-tinted color scheme. The image is positioned on the left side of the slide, partially overlapping the text.

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# REACH: IMPLICATIONS FOR SMEs AND NON-EU SUPPLIERS

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# REACH: SMEs AND NON-EU SUPPLIERS: OUTLINE

1. Why significant compliance burden?
2. Is REACH a trade barrier?
3. Costs and staffing issues for SMEs
4. REACH as a competition tool
5. Withdrawal of SMEs from market
6. Background to clarification of OR rules
7. Recent changes in OR rules
8. Outstanding questions for non-EU suppliers
9. Conclusions

# REACH: THE BURDEN OF COMPLIANCE

- Burden of proving safety of substances moved squarely onto industry
- Supply chain management requirements, even when not subject to direct obligations
- Mandatory cooperation with competitors
- REACH a moving target
  - ✓ REACH still being interpreted and understood (by the Commission as well as industry!)
  - ✓ Practical consequences not properly thought through
  - ✓ ECHA Guidance regularly revised to “fix” practical issues
  - ✓ Exempt - yes or no?

# REACH: THE BURDEN OF COMPLIANCE

## ➤ Unclear

- ✓ Guidance and Regulation conflict
- ✓ requirements to Register reacted form of monomers in polymers
- ✓ Articles provisions inaccessible

## REACH: A TRADE BARRIER?

- Representations by 24 Governments in WTO Technical Barriers to Trade Committee
- REACH arguably creates trade barriers because:
  - ✓ discriminates against non-EU suppliers exporting substances to EU (Article 2.1 TBT Agreement);
  - ✓ unnecessarily burdensome, (not least restrictive measures: Article 2.2 TBT Agreement) complex and unclear, particularly prejudicing SMEs.
- REACH is the ‘biggest issue in the history of the World Trade Organisation’s Technical Barriers to Trade Committee’ (USTR)

## REACH: COSTS FOR 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)

# REACH: ECHA VIEW ON SMEs REALISTIC?

## ➤ ECHA SME Scenario (MEMO/08/360, p.2)

“Headquartered in Colmar in the East of France, this company produces microfilament technical textiles and has 50 employees. Implementing measures linked to REACH were initiated in January 2007.

In April and May 2007, suppliers were contacted about REACH.

A particular challenge was to get more safety and environmental information about the hazardous substances used in the factory.

A timetable was created, starting with the opening of the pre-registration period of 1 June 2008.

In addition to external help from the Strasbourg Chamber of Commerce, Evolon received support from the parent company which had appointed someone with specific responsibility to coordinate operations for REACH.

The company has found establishing a comprehensive inventory of all the substances that come into and go out of the premises very useful and recommends this to other companies that will be affected by REACH”.

# REACH: THE REALITY?



## REACH: COSTS AND STAFFING ISSUES FOR SMEs

- Real SME costs issue is burden of compiling dossiers and cooperation on data sharing for registration:
  - ✓ Estimated costs at least EUR 100,000 – 200,000 per substance
- Particular problem for niche specialty product producers
  - ✓ reduced opportunities to offset registration costs of lower value substances by cross-subsidising
  - ✓ Few/no other producers so limited/no costs sharing potential for data gap filling
  - ✓ Extent of data requirements linked to volumes not company services
- Adequate staff to even understand REACH, let alone comply with it?

# REACH: TOOL FOR COMPETITION

➤ US family owned, 75 employee, cleanings and coatings operation

- ✓ “We can’t afford REACH”
- ✓ “Our staffing levels preclude adequate coverage of REACH compliance topics even insofar as basic knowledge acquisition of a complex regulatory scheme. Our regulatory cost rates and overall cash flow preclude engagement of consulting firms to adequately ramp up for REACH purposes”.

➤ Executive Director for Product Stewardship of global silicones leader

- ✓ “We are using REACH in a positive manner, as a driver for internal innovation programmes”.
- ✓ Enhance brand reputation/industry leadership
- ✓ Set up for adoption of REACH equivalent in third countries

## REACH: WITHDRAWAL OF SMEs FROM MARKET

- “SMEs are disproportionately impacted to the point of altogether losing access to the market”.
  - ✓ US mission in the EU suggested 10% withdrawal of substances in the EU market (conservative)
  - ✓ At least 20% withdrawal realistic (plus non-mass market ‘invisible’ products)
  - ✓ Alternatives available? (biocides example)

## REACH: NON-EU SUPPLIER - BACKGROUND TO CHANGES IN OR INTERPRETATIVE GUIDANCE

- Non-EU based suppliers cannot register directly
- May appoint OR to avoid disclosure of CBI, direct control over preserving EU markets
- Practical effect of REACH on non-EU supply chain not properly considered
- OR requirement a discriminatory trade barrier for non-EU suppliers (vis-à-vis EU based competitors)?
- Pressure from non-EU based industry on Commission and ECHA to (re)-interpret Regulation fairly
- “Third country concerns have not been factored into the legislative process” (U.S. Ambassador to the EU, C. Boyden Gray, 8 June 2006)

## REACH: NON-EU SUPPLIERS: APPOINTMENT OF OR BY MORE THAN ONE SUPPLIER OF SAME SUBSTANCE

- Requirement for separate registration for each non-EU supplier of same substance
- OR not required to aggregate export tonnages of all non-EU suppliers it represents for relevant substance
  - ✓ avoids non-EU suppliers being disadvantaged by heavier and earlier registration requirements than EU based M/Is of equivalent tonnages
- Eligibility for SME registration fee reduction based on size of each (not aggregated) supplier represented by OR (Article 12, Regulation (EC) 340/2008)
  - ✓ avoids non-EU suppliers missing fee reductions enjoyed by EU based competitors of equivalent size

## REACH: NON-EU SUPPLIERS: APPOINTMENT OF OR BY INDIRECT EXPORTER

- Can a non-EU manufacturer appoint an OR for tonnages of a substance exported into EU territory ‘indirectly’ (by those in manufacturer’s non-EU downstream supply chain)?
- May 2008 ECHA Registration Guidance: Indirect exporter can appoint OR if export undertaken by non-EU based distributor, but what about other non-EU downstream actors?
- 4th meeting of REACH CAs June 16-17 2008 confirms Commission interpretation that indirect exporter can appoint OR where export undertaken by downstream non-EU based formulators or articles producers:

## REACH: NON-EU SUPPLIERS: APPOINTMENT OF OR BY INDIRECT EXPORTER

‘REACH does not distinguish between direct and indirect imports into the EU...As long as it is clear for which imports the OR is responsible, it does not matter what are the steps or supply chain outside the EU between the manufacturer, formulator or producer of an article and the importer in the EU’ (suggested amendment to ECHA Registration Guidance).

- Non-EU manufacturer can ask downstream actor to agree to let it register its tonnage rather than actor appoint its own OR:
  - ✓ strategically preferable: avoid passing CBI to downstream non-EU actor?
  - ✓ Results in equal treatment of non-EU and EU manufacturers

## REACH: NON-EU SUPPLIERS: CHANGING YOUR OR

- Latest May 2008 ECHA Registration Guidance:
  - ‘If a “non-Community manufacturer” decides to change his only representative, the successor will have to submit a new registration dossier, as there is no link between the two only representatives who are separate legal entities’ (section 1.5.3.4, page 23).
- Unfair restriction and burden on non-EU suppliers, particularly compared with EU manufacturers

## REACH: NON-EU SUPPLIERS: CHANGING YOUR OR

- Amendment to ECHA Registration Guidance suggested at CAs meeting:

‘If a “non-Community manufacturer” decides to change his only representative, the successor can submit an update of the earlier registration dossier provided that the earlier only representative agrees to the change’ (return to position in June 2007 Registration Guidance).

- Need to prove agreement with previous OR in update
- Appropriate provisions in OR agreement dealing with change of only representative

## REACH: NON-EU SUPPLIERS: OR POINTS STILL TO BE CLARIFIED - ALL OR NOTHING?

- ECHA states at CA meeting that following question needs clarification:
  - ✓ ‘Is the whole volume of a substance manufactured by a “non-Community manufacturer” and exported to the EU (directly or from any point in the Community supply chain) to be covered by the registration of the only representative he has appointed?’
- Meaning of question unclear
- MEANING 1: That an OR appointed by a non-Community manufacturer cannot register tonnages sold to some downstream non-EU actors only but not to others

## REACH: NON-EU SUPPLIERS: OR POINTS STILL TO BE CLARIFIED – ALL OR NOTHING?

- ✓ ability of indirect exporter to appoint an OR would depend on obtaining agreement of **all** non-EU downstream actors not to appoint their own OR
- ✓ MEANING 2: That a non-EU supplier (whether direct or indirect exporter) which appoints an OR could decide that a certain volume of relevant substance will not be included in OR's registration but left to EU based importer to register
- ✓ generally assumed to date that OR would register **all** appointor's exports of substance (except tonnages registered by another OR appointed by non-EU based downstream actor)

## REACH: NON-EU SUPPLIERS: OR POINTS STILL TO BE CLARIFIED - LATE PRE-REGISTRATION

- ECHA states at CA meeting following question:
  - ✓ ‘What are the conditions under which an only representative can benefit from Article 28.6 of the REACH Regulation (late pre-registration), if any?’
- Wording of late registration provision aimed at EU based entities only?
- But OR shall comply with ‘all other obligations of importers under this Regulation’ (Article 8(2))
- Unlike EU M/Is, difficulty of telling whether OR is representing a company first manufacturing or importing post 1.12.08 or not

# CONCLUSIONS I

- Ongoing representations that REACH a trade barrier - no substantive case yet brought
- Changes to (non-binding) Guidance driven by industry pressure
- Regulators making it up as they go along “firefighting”
- Inadequate concessions for SMEs
- REACH compliance simply beyond SME resources
- Disappearing markets fast approaching

## CONCLUSIONS II

- OR clarifications welcome but lack of legal certainty, both to date and on outstanding issues, problematic for REACH compliance:
  - ✓ Separate registration requirement = cost implications for ORs who already agreed to represent several non-EU suppliers of same substance
  - ✓ OR appointment by indirect exporter clarification too late? Non-EU downstream actors already appointed ORs prior to pre-registration
  - ✓ OR agreements already executed:
    - without provisions permitting update by new OR
    - too late to decide to now exclude tonnage of certain EU importer

# REACH Beyond Pre-Registration

## *Complimentary Webinar*

- **4 December 2008, 1600 - 1730 CET (1000 AM EST)**
- **Led by:** Steptoe REACH Team and guest speaker, Malachy Hargadon, Environment Counselor, Delegation of the European Commission to the United States
- **Topics:**
  - ✓ Taking stock of pre-registration
  - ✓ Options in the event of pre-registration deficiencies
  - ✓ What's next?
    - Managing SIEF/Consortia activities
    - Data/cost-sharing in practice
- **To register:** Email [REACH@steptoe.com](mailto:REACH@steptoe.com)
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