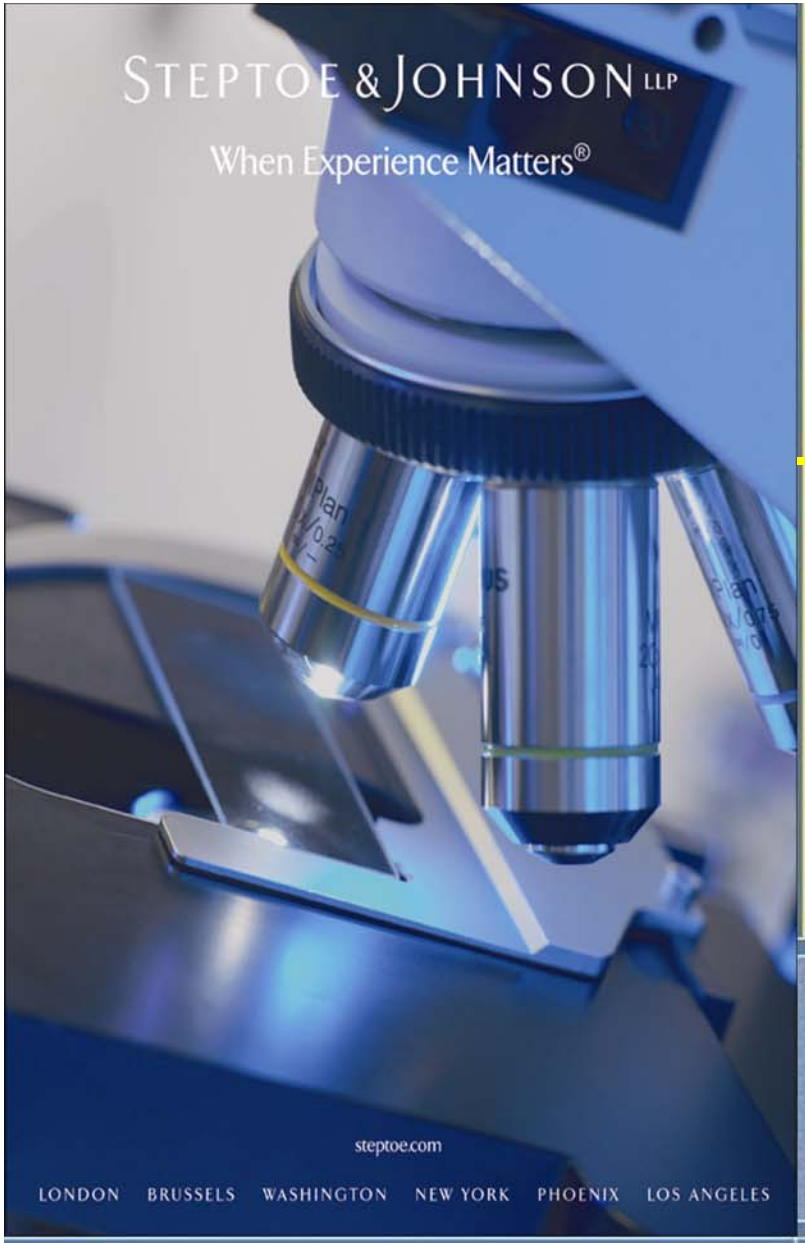

Lead-up to REACH Pre-Registration -- What, and Who, are covered By REACH?

(and what to do about it)

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"REACH in Practice" Conference
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STEPTOE & JOHNSON LLP

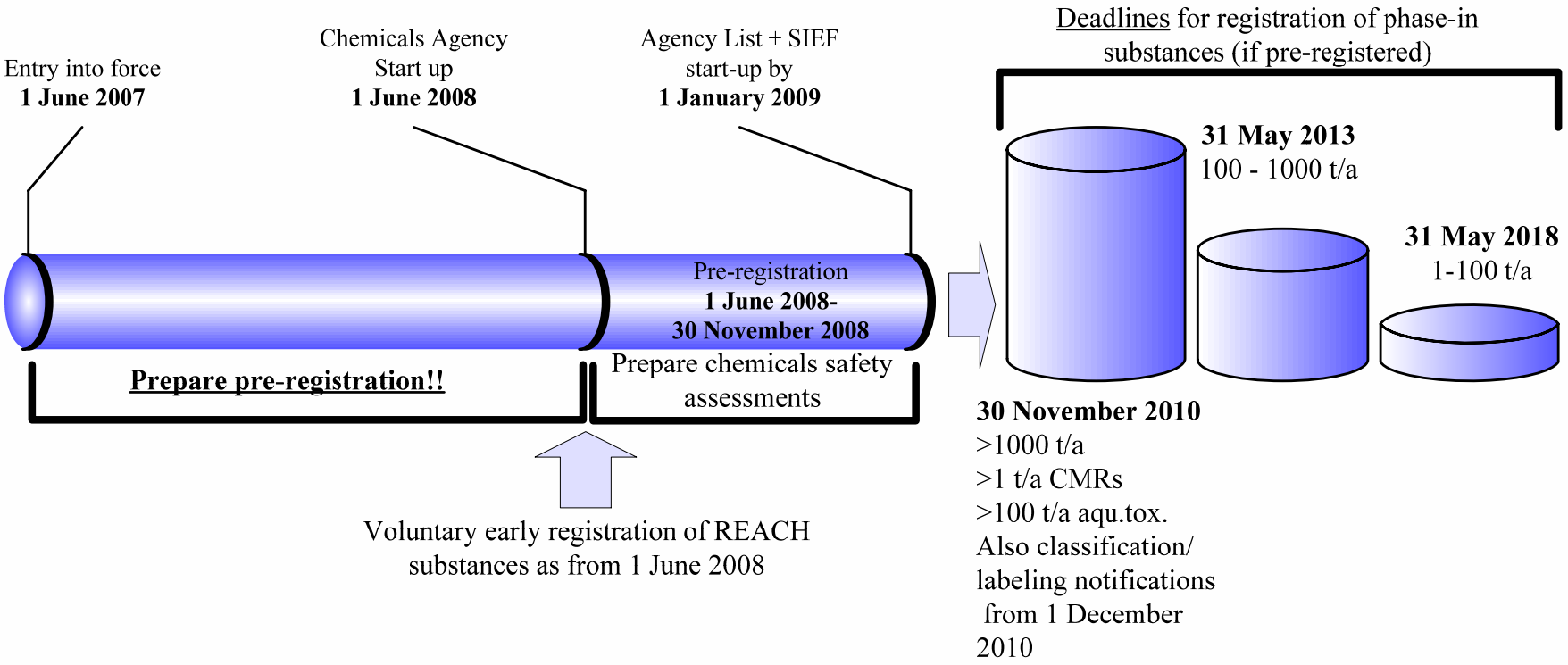
Key Issues

- June 1, 2007: Entry into force of REACH (Regulation 1907/2006)
- We are here today because ~ 100,000 chemical substances exist on EU market since before 1981 (EINECS), a great many of which have not been fully tested for risks to humans and environment
- Burden now on industry to demonstrate safety to enable these substances to stay on the market (no data, no market)
- REACH establishes the process, and timetable, for substances to be registered, evaluated and, if their risks are excessive, to be restricted or mandatorily substituted by available safer substances
- Focus on ~ 30,000 existing substances placed on EU market $\geq$ 1 tonne/yr; est. 140,000 entities will become registrants

First Session

- First session today focuses on what companies need to do between today and June 1, 2008, to ensure that substances they place into the EU market are registered in most efficient and cost-effective manner
- First concern is that existing substances that need to be registered can benefit from transitional registration deadlines starting in 2010 and stretching to 2018 ("phase-in" substances)
- Pre-registration between June 1 and Nov 30, 2008 essential! (if miss pre-registration, then substance treated as “new“ – mfr. or importer must withdraw substance from market until full registration, including submission of all required test data, is complete)

Essential Dates for REACH Compliance



First Practical Assessment

- Who is affected by REACH?
  - ✓ Every EU Manufacturer and Importer of a "substance", whether on its own or in a preparation, and in certain conditions also substances in "articles" → Registration, Authorisation of SVHC, Restrictions …
  - ✓ (EU) Downstream Users (DU) → Information, potential CSR
  - ✓ Exporters to EU Market (substance, preparation, article) → Compliance Assurance (No data, no Market); Protection of CBI; Potential Registration through "only representative"; REACH Cost Minimisation (US largest exporter of substances to EU market – 19.5%)
  - ✓ Every company here today fits one, often several roles – REACH has substantial impact on all parties involved in substances being placed on EU market

Other Up-Front Assessments to Determine Scope of Obligations

- Assessment of scope of substance coverage / exemptions (medicinal, food, plant protection, biocides, waste) (Art 2) and reduced requirements for other substances (use in cosmetics, isolated intermediates) Art 14(5); Art 17/18
- Assessment whether substance is a "preparation (in container)" or in an 'article' Art 3(2) and (3)
- If in 'article', assessment of registration vs. notification requirements for substances released from articles Art 7
- Assessment of structural options for efficient registration process (taking into account for each substance any related EU manufacturing entity(ies) and/or related/unrelated importer/sales entity(ies); possible 'only representative' to replace importer obligations)

REACH Substance Coverage

- **Substance**: "a chemical element and its compounds in the natural state or obtained by any manufacturing process, *Including* any additive necessary to preserve its stability and any impurity deriving from the process used, but *Excluding* any solvent which may be separated without affecting the stability of the substance or changing its composition." Art 3(1)
- Includes certain monomers in polymers Art 6(3) (monomer registration = proxy for polymer registration; CSR on monomer to cover risks of polymer)
- Check EINECS – these substances must be REACH registered if m/i $\geq$ 1 tonne
- RIP 3.10* - TG for Identification and Naming Substances (same or different substance to register?)
- Attention: nomenclature mistakes in EINECS, nomenclature not same in all jurisdictions, plus inconsistent classifications, e.g. CMRs
- Your substances for EU market are covered … unless already "notified" or exemption applies. But attention to the exemptions!

Exemptions

- REACH exemptions are difficult beasts – some still being tamed as possible.
- Certain exemptions established from first draft 2003 – exemption clear but legislative basis not: Annex IV- "sufficient information is known"; Annex V- certain classes of natural and other substances, e.g., minerals, ores, gases, oil, coal -- unless chemically modified, and basic elemental substances (oxygen, nitrogen, hydrogen) – but these Annexes will be reviewed w/i 1 year.
- Radioactive substances and non-isolated intermediates exempt (but see Art 17/18 for reduced registration of on-site and transported isolated intermediates)
- Waste substances exempt, but attention to EU waste definition (substance "which holder discards or intends or is required to discard"): is by-product substance sold on to another party?

Exemptions

- Notified "new" substances under Dangerous Substances legislation since 1981 deemed registered (but additional data required if next higher tonnage band reached, and still subject to supply chain information requirements) Art 24
- Certain principles of exemption, e.g., "adequately regulated" substances under separate sectoral EU legislation, apply but the specific exemptions have been subject to lobbying and results not consistent:
  - ✓ Substances used in medicinal products within scope of Reg. 726/2004 ... are exempt – but read literally: substances used as processing aids, growth media, etc. not exempt, nor are substances used in medicinal products not covered by specified EU legislation (e.g. magistral formulas)

    Medicinal substances which have other, non-exempt uses are exempt only as regards their covered medicinal use (i.e., 50 of 150 tonnes m/i for other uses must be registered at 50 tonne level)

Exemptions

- Same "adequately regulated" principle applies for certain substances used in food or feedingstuffs:
  - ✓ Food flavourings per Dir 88/388 and Decision 1999/217 – but many flavourings are also natural fragrances (albeit chemically modified) so tonnage used as e.g., fragrances in cosmetics, not exempt
- Cosmetics, an issue from early in REACH drafting; exemption considered along medicinal or food lines due to separate extensive regulatory regime/testing involved – but testing only for human health risks.
  - ✓ REACH applies, but focuses on environmental risks of substances approved under EU Cosmetics Directive 76/768 (CSR does not have to address human health risks), so duplication avoided
  - ✓ vast majority of substances used in cosmetic products (e.g. surfactants, emulsifiers, solvents, colorants, etc.) also used by other industries and EU chemicals legislation has always applied to these -- this will continue to be the case under REACH

Exemptions

- Complications arise with "regarded as registered" substances (Art 15): plant protection and biocidal substances
  - ✓ Active substances and co-formulants "for use in plant protection products only"
  - ✓ Active substances "for use in biocidal products only"
- "Only" = exclusively; Commission understands it is "rare" that, e.g., a biocidal substance, is used exclusively in BP (also used in many other products, from paints to shampoos), so exemption as presently worded will benefit few, if any at all.

Exemptions

- Compare impact of exemption phrasing for PPP/BP substances if "dual use" exists versus impact for medicinal substances with dual use:
  - = Exemption for medicinal use maintained but registration needed for volume for other non-exempt uses (dual use merely reduces the volume exempt for medicinal substance), versus
  - = Dual use totally eliminates exemption for PPP and BP substances (registration of full tonnage even if only slight other usage)

Exemptions – Other anomalies

- Even if exclusive PPP or BP use and "regarded as being registered", the substance mfer / importer is made a mandatory participant in the SIEF and thus subject to its data-sharing rules! Art 29 (no such effect with medicinal substances)

  In principle, subsequent registrants can request, and must receive (upon payment), data-referral rights

- Implications of these "exemptions" were not foreseen (some just learning now); partially result of late amendments and bad drafting in final stages of decision-taking; problems of inconsistency amongst exemptions and with general principles for exemption. Serious need for serious amendments

  E.g., bad drafting: PPP co-formulants exemption formulated to exclude exemption in practice (not covered by Annex I of Directive 91/414

Exemptions

How to resolve exemptions problems?

- **Amendment of Art 15 of REACH itself? Not within current review provisions but review of "overlaps" by mid-2012**

- **Amendment of the Sectoral Legislation? Might affect scope of substances covered by exemption, but would not counteract the "only" limitation in Art 15**
  - ✓ **E.g. draft EP Amendment: "Where a co-formulant is used in a plant protection product that has been authorised under Directive 91/414/EEC1 or this Regulation it shall be regarded as being registered in accordance with Article 15(1) of Regulation (EC) No 1907/2006 for the specific use in plant protection products."**

    PPP only; would concern co-formulants that are used exclusively for PPP formulations
- **Essential for sectors to assert need for REACH amendments to establish consistency in exemption effects**

Conclusions

- REACH enters into force today
- Some 30,000 substances already on EU market ≥ 1 tonne must be duly registered, or be withdrawn from the EU market
- EU Manufacturer and Importer liable for registration, but Exporters to EU have vital interest in the registration process and may potentially register through "only representative"
- Exemptions exist, but practical effect of these exemptions may be quite limited – need to be amended
- All companies involved in placing chemical substances on the EU market must ready themselves to deal with REACH as adopted.

What's next?

- So, now that we know what substances need to be registered under REACH by whom, let's look more in depth at the most efficient structure for registration.