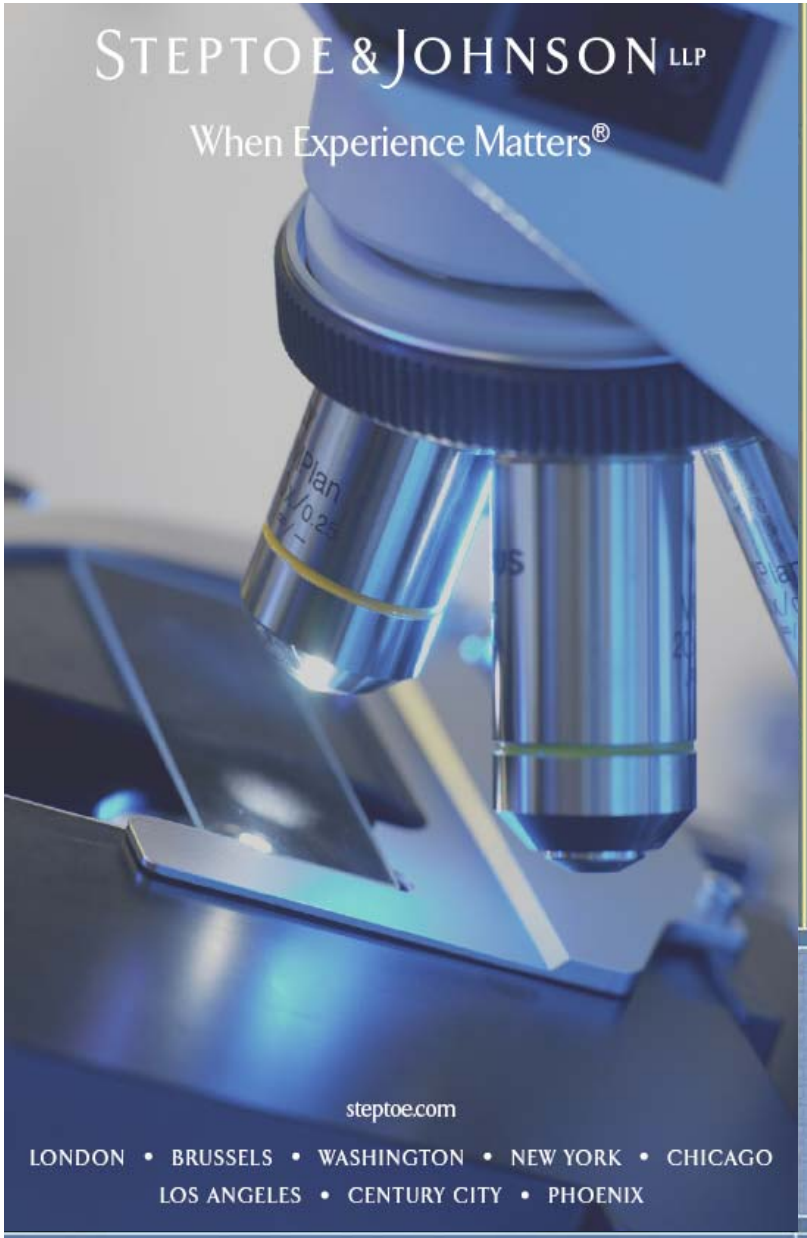


REACH Essentials ~ How To Keep Your Product On The Market

Darren Abrahams
Barrister

8 May 2008
ISSA Interclean®, Amsterdam
"Green and Clean - Confusion?" Seminar

STEPTOE & JOHNSON LLP

Green Objective

- **New EU regulatory regime** for chemicals (replaces 40 measures) explicitly based on *precautionary principle*.
- Concerns **approx. 30,000 substances** (on own or in preparation or articles)
- Comprehensive **toxicological and environmental effects data** must be compiled by *each* EU manufacturer or importer of substance to EU and be **registered** with ECHA: "**no data, no market**".
- By 30 November must ensure **pre-registration** (by the EU manufacturer or importer) of all the substances you use, manufacture and import.
- This means that you need a **complete substance inventory** ASAP.
- Integrated compliance "strategy" is essential with top management buy in.

What is covered?

All Substances (on own or in a preparation):

- 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

Certain narrow registration exemptions e.g. for certain substances which occur in nature, *if they are not chemically modified*, actives used in biocidal products *etc.*

What is covered?

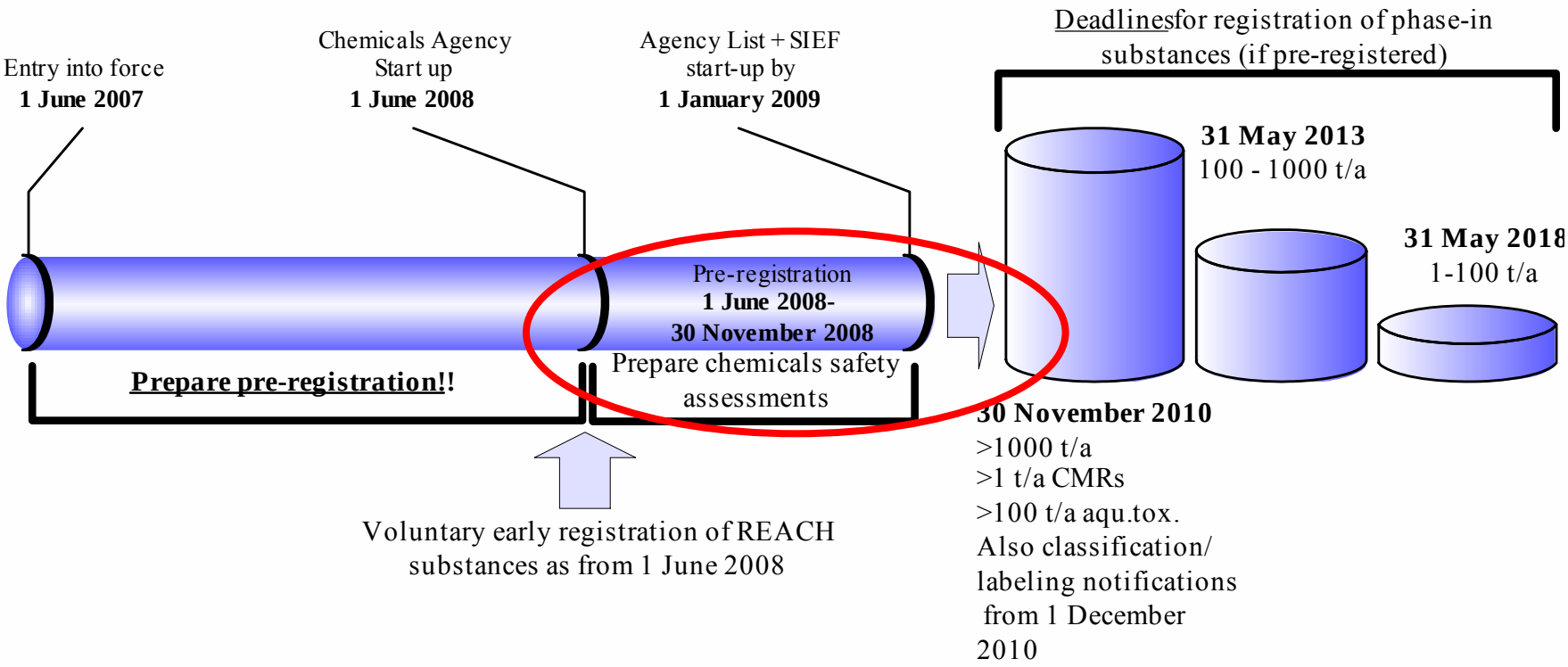
Substances in Articles (finished products):

- an object which during production is given a special shape, surface or design which *determines its function to a greater degree than does its chemical composition*.

- Substances must be registered if the substance:
  - present in the articles in quantities totaling ≥ 1 tonne/producer or importer, per year,
  - is *intended* to be released under *normal or reasonably foreseeable conditions of use*, and
  - has not been registered for the particular use.

- SVHCs at specific concentrations, in articles, must be notified if cannot ensure against release (even at end of life)

Key Timelines



Who must register?

- Each EU manufacturer who makes a (non-exempt) substance in quantities of ≥1 tonne/year
- Any entity who makes or assembles an article in EU, or imports an article into the EU (meeting criteria).
- Each importer who imports a substance in quantities of ≥1 tonne/year.

Registration is:

- *per* legal entity
- Non-EU companies cannot Register (Importer or Only Rep.)

"Only Representative"

Non-Community manufacturers may appoint "Only Representatives."

- The OR assumes the responsibilities of a registering importer, including:
  - ✓ Pre-registering and registering substances
  - ✓ Participating in SIEF(s)
  - ✓ Acting as a liaison within the supply chain
  - ✓ Overseeing the preparation of registration dossiers and submitting to the authorities
  - ✓ Managing and retaining documents for 10 years.
- When OR used the existing (true) importer becomes a Downstream User for REACH.

“Only Representative”

- “OR”s should have REACH specific legal/regulatory/technical expertise (contrast with importer).
- REACH compliance would be centralised in one trusted entity, facilitating oversight.
- No confidentiality concerns (no conflicting commercial interests).

How To Pre-Register

Pre-registrants submit the following to ECHA:

1. identity of the pre-registrant (or OR/third party representative);
2. envisaged deadline and tonnage band;
3. name of substance, including EINECS and CAS if available; and
4. substances for read-across/(Q)SARs.

No Pre-Registration fee.

How To Pre-Register

By **1 January 2009** ECHA will publish a list of pre-registered substances.

1. Downstream users (DUs) will check the list.
2. If the DU's substance does not appear on the list, he may notify ECHA of his interest in the substance, his contact details, and the details of his current supplier (within 6 months).
3. The Agency will add the substance to the list.
4. On request, the Agency will give the DU's contact details to a potential registrant.

Downstream Users

What if I am a DU?

Who is a DU?

- natural/legal person established within EU
- who uses a substance, on its own or in a preparation
- in the course of his industrial or professional activities.

Could include formulators of preparations, producers of articles etc.

REMEMBER: The DU is someone other than the "manufacturer" or the "importer":

A distributor (including retailer) or a consumer is **not** a downstream user.

Managing Your Supply Chain

As a Downstream User:

Check information from your supplier (Safety Data Sheet, exposure scenario or other) to make sure your use is safe.

↓

Check that you comply with any restrictions or authorization conditions.

↓

Pass relevant information on hazards, risk management measures to your supplier.

↓

Pass information to industrial and professional customers on safe use.

Safety Data Sheets (SDS), Chemical Safety Reports (CSR) AND Exposure Scenarios (ES) (1)

- DU **will receive** a safety data sheet (SDS) from a supplier when a substance is:
  - ✓ (or preparation) classified as dangerous;
  - ✓ persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) (criteria in REACH Annex XIII); or
  - ✓ included in the list of substances subject to authorisation (for a reason other than either of the above two).

- A SDS **may be requested** from a supplier when a preparation is not dangerous, but contains:
  - ✓ in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and ≥ 0,2 % by volume for gaseous preparations at least one substance *posing human health or environmental hazards*; or
  - ✓ in an individual concentration of ≥ 0,1 % by weight for non-gaseous preparations at least one substance that is PBT or vPvB (criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) *in the list of substances subject to authorisation*; or
  - ✓ a substance for which there are *EU workplace exposure limits*.

Safety Data Sheets (SDS), Chemical Safety Reports (CSR) AND Exposure Scenarios (ES) (2)

Any supplier of a substance/preparation who does not have to supply a SDS must provide the recipient with the following:

(a) the registration number(s), if available, for any substances for which information is communicated under points (b), (c) or (d);

(b) if the substance is subject to authorisation and details of any authorisation granted or denied in this supply chain;

(c) details of any restriction imposed;

(d) any other available and relevant information about the substance that is necessary to enable appropriate risk management measures (RMM) to be identified and applied including specific conditions resulting from the application of section 3 of Annex XI (Substance-tailored exposure-driven testing)

Safety Data Sheets (SDS), Chemical Safety Reports (CSR) AND Exposure Scenarios (ES) (3)

- A chemical safety assessment (CSA) must be performed and a chemical safety report (CSR) completed for all substances subject to registration in quantities of **10 tonnes** or more per year per registrant.

- **A CSA does not need to be performed** for a substance which is present in a preparation if the concentration of the substance in the preparation is less than the lowest of any of the following:
  - ✓ (a) the applicable concentrations defined in the table of Article 3(3) of the Dangerous Preparations Directive;
  - ✓ (b) the concentration limits given in Annex I to the Dangerous Substances Directive;
  - ✓ (c) the concentration limits given in Part B of Annex II to Dangerous Preparations Directive;

- **If the CSA shows that the substance meets the criteria for classification as dangerous** in accordance with the Dangerous Substances Directive or is assessed to be a PBT or vPvB, the **CSA must include an exposure assessment with resulting exposure scenario (ES).**

Safety Data Sheets (SDS), Chemical Safety Reports (CSR) AND Exposure Scenarios (ES) (4)

DU should:

1. Identify the substances and preparations used in their industrial processes.
2. Ask their supplier whether they have already established use and exposure categories/exposure scenarios for the substance/substances in preparations that they supply.
   - DU may also check SDS provided to them to see whether their uses are already covered in the SDS.
3. If their uses are not yet covered, DU may provide to their supplier information to develop an exposure scenario/use and exposure category.

Information up and down the supply chain

- The ES may cover one specific process or use or several processes or uses as appropriate.
- A downstream user may provide their supplier with information to develop an exposure scenario/use and exposure category for its specific use.
- A downstream user may choose to keep its uses of substances confidential.
  - ✓ It will prepare its own CSA and ES (if necessary)
  - ✓ It must notify these uses to the European Chemicals Agency (ECA).

Further Big Picture Issues

- Beyond registration, use of SVHCs which must be authorized - potentially substituted. Consider effect of candidate list.
- Compulsory sharing of data in a SIEF - are you an owner or a purchaser?

"Take Home" Action List

- **Before pre-registration:**
  - ✓ Prepare an inventory
  - ✓ Find out what will be supported upstream (get binding undertakings)
  - ✓ Determine which substance, preparations, or articles are covered by REACH
  - ✓ Prepare a time-table
  - ✓ Gather the data you have available
  - ✓ Set-up a data-handling system
- **Before and during registering:**
  - ✓ Figure out what data/information will be required
  - ✓ Determine how to source the necessary data
  - ✓ Determine who may be its future partners how it will handle selling/buying data.

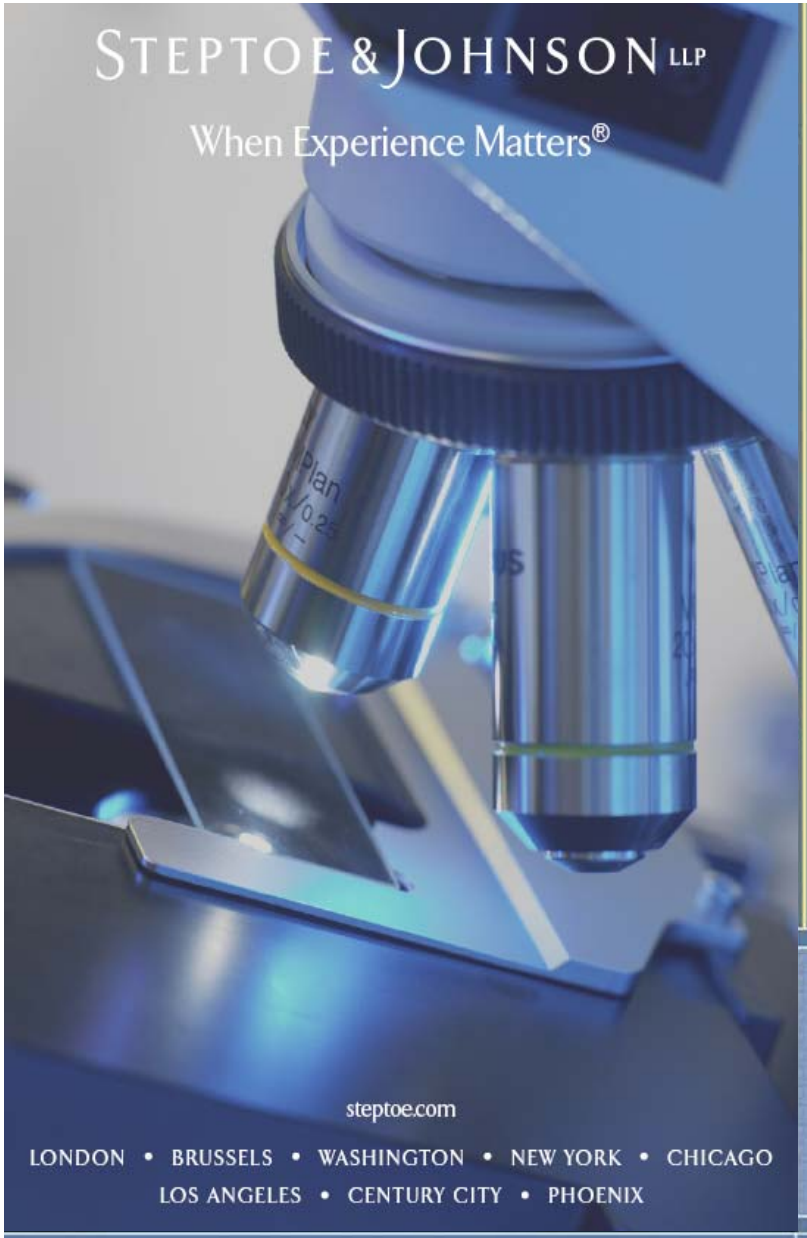
"Take Home" Strategic Messages

REACH not <u>just</u> a compliance issue. Major companies also see it as an opportunity for:

- Company positioning (enhanced product/brand reputation)
- Customer outreach
- Customer loyalty
- Industry leadership (reputational, political and marketing benefits)
- Proactive Business Planning (products, competition and sectoral re-structuring)
- REACH Compliance = "safety certificate" (long-term confidence and purchase of products)
- REACH requires contact with suppliers, co-producers, distributors, customers, authorities, policy-makers, NGOs - these contacts can be used to your benefit.

Useful Information

Useful Information



Thank You

Darren Abrahams
Barrister

dabrahams@steptoe.com

STEPTOE & JOHNSON LLP