

A close-up photograph of a microscope's objective lenses and eyepiece, set against a blue-tinted background. The image is used as a visual element for the Steptoe & Johnson LLP logo and tagline.

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Lead-up to REACH Pre-Registration

Who Must / Should Register? (And How to Do It Efficiently)

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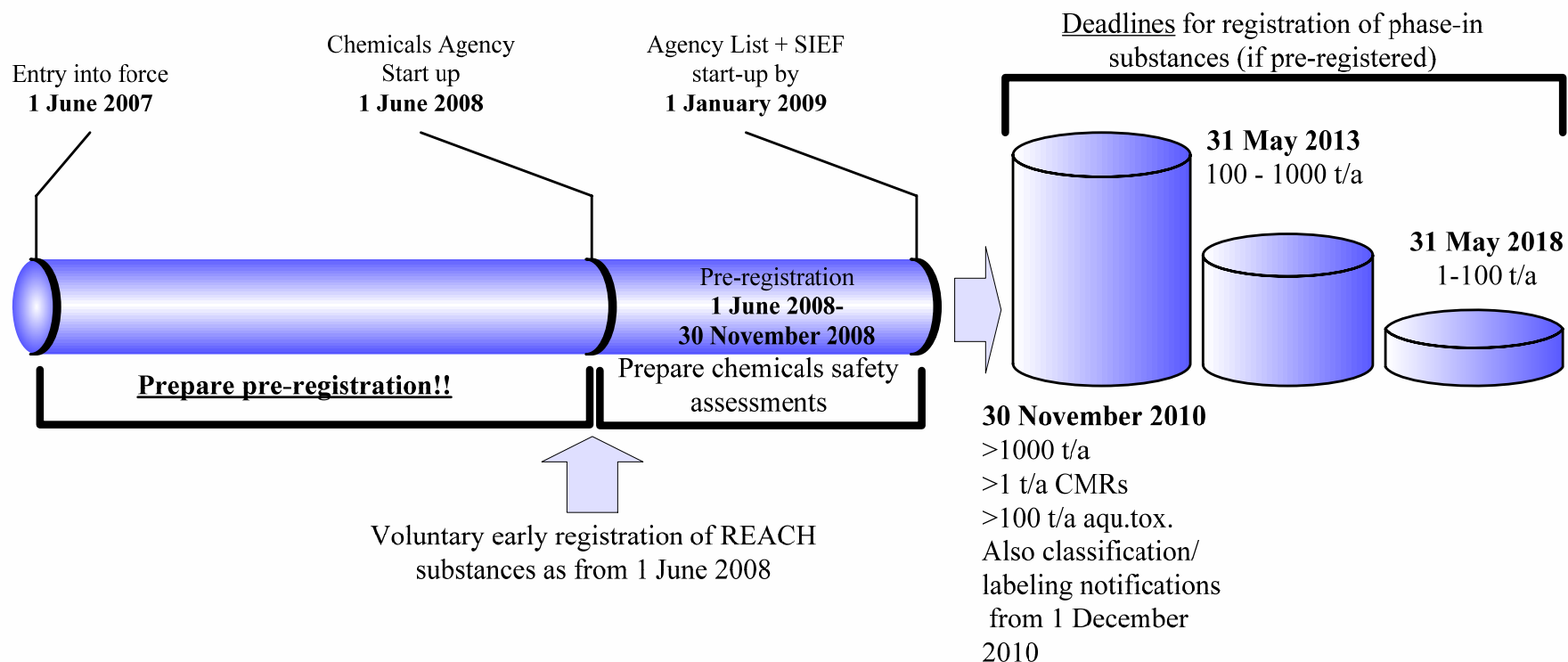
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Essential Dates for REACH Compliance



Practical Assessment

- Who Must Normally (Pre-) Register the Substance under REACH?
 - ✓ Every EU Manufacturer and Importer of a “substance” placed on EU market \geq 1 tonne/year, whether on its own or in a preparation (Art 6), and in certain conditions also substances in “articles” Art 7
- Who May Register the Substance?
 - ✓ Exporter to EU Market (substance, preparation, article); Option to register through “only representative” who replaces EU importer’s responsibility Art 8
- Every company here today fits one, likely several roles, so important to decide who must, and who should, register according to specific market circumstances and need to protect company data interests/minimize costs

Perspectives on (Pre-) Registration Burden – EU Mfr..

➤ EU Manufacturer Perspective

No option, must (pre-)register, but relatively straightforward because you know precisely what you are making, in what quantities, probably for most end uses – just need the necessary test data for registration in accordance with quantity produced (total including quantity for export)

(Technical dossier = phys-chem properties, tox and ecotox data per tonnage band; plus CSR if > 10 t/yr → human health hazard assessment, environmental hazard assessment, PBT or vPvB, exposure assessment (all known uses), risk characterisation ... Arts 10, 12, 14; Annexes I, VII-XI)

Perspectives on (Pre-) Registration Burden – EU Importer

- EU Importer Perspective – more complex
- Each importer has legal obligation to register each substance it imports, according to volume imported
 - ✓ Rare that single substance is imported, more likely preparations that contain multiple substances (dangerous or >2%)

Importer/retailer, importing tens if not hundreds of products that are preparations (toiletries, wide range household products), all of whose constituent substances must be registered by the importer if ≥ 1 tonne/yr
 - ✓ Importer must obtain, from each overseas supplier, details on formulation of each imported preparation and weight (sufficient to calculate precise weight of each substance in each product unit), because importer must register for total volume of each substance imported from all suppliers (many products have common basic ingredients and importer will surpass 1 tonne threshold)
 - ✓ Substances in packaging also covered!

Perspectives on (Pre-) Registration Burden – EU Importer

- Beyond your product formulation to calculate weight of each constituent substance in each preparation (or in article with substance release), importer must obtain your data necessary for registration (Confidentiality and Disclosure issues)
- You may only export small volume, but importer may import total large volume from multiple suppliers, thus needing to obtain more data than you may have
- Not only CBI concern but importer likely to request its supplier(s) to share its registration fees and cost of acquiring supplemental data for its registration (data held by other suppliers or to be newly generated)
- Even if Importer gets what data it asks for from each supplier, may face problems with different substance names, different purities, different impurities, different classifications, different labelling recommendations, different quality of test data, etc. Importer may not be equipped to handle this.
- Importer's data and financial needs will place burden on relationship but, worse, importer could finally decide registration burden is too great and drop the business, leaving you without an importer (restructuring of import/distribution sector, especially loss of SME importers: Need Importer Warranty of REACH (pre-)Registration)

Perspectives on (Pre-) Registration Burden – Non-EU Exporter

➤ Non-EU Exporter Perspective – perhaps most complex situation overall (several scenarios)

1. Exporter only (from US and/or other non-EU locations – China?) with no EU sales entity/importer

Considerations:

-- Data-sharing with independent (“unrelated”) importer (CBI concern)

-- Cost-sharing with importer

x # of importers!

Perspectives on (Pre-) Registration Burden – Non-EU Exporter

2a. Exporter + related EU sale entity(ies)/importer(s)

Considerations:

- Reduced data-sharing concern but each sales office must register what it imports (5 MS offices = 5 co. registrants; 27 MS offices = 27 registrants, each for own sales quantity)

- Some cost efficiencies from joint registration

2b. (More often) Exporter + related importer(s) in key MS markets and unrelated importers /distributors in others

- Data-sharing concerns

- Cost-sharing with unrelated

Perspectives on (Pre-) Registration Burden – Non-EU Exporter

- 3. Exporter with related importers, unrelated importers and EU manufacturing site(s) (likely manufacturing and importing different products for complete EU market product range)
 - mfr. registration
 - related importer registration
 - unrelated importer registration (with your data)
 - = Data-sharing, Cost-sharing, Huge management exercise to ensure REACH compliance

Perspectives on (Pre-) Registration Burden – Non-EU Exporter

➤ Administration problems get worse:

Each intending registrant/entity of phase-in substances must separately pre-register 1 June-30 Nov 2008 and automatically be assigned by Agency to Substance Information Exchange Forum (SIEF) per substance

SIEF is context within which intending registrants are obliged to share data (and costs), like existing substance consortia/task forces but mandatory sharing and open shop: no exclusions

(may also include DUs and other data holders including NGOs)

Perspectives on (Pre-) Registration Burden – Non-EU Exporter

- So, in scenario # 3, Exporter must manage and ensure REACH compliance by
 - EU production unit(s), and
 - related EU importers, and
 - unrelated EU importers(each legal entity a separate (pre-) registrant and which will be assigned to a SIEF for each substance they place on EU market)

Meaning: If exporting range of products containing total 75 substances, have to deal with collection of above entities taking part in 75 SIEFs wherein they will holding and possibly negotiating the exchange and terms of sharing your company data, possibly also purchasing referral rights on any missing data

Perspectives on (Pre-) Registration Burden – Non-EU Exporter

➤ Additional concerns:

Unrelated importers likely to receive data from multiple suppliers (your competitors), so increased concern about disclosure but also how importer deals with different quality data, different C&L, different end-uses, etc. Is your importer relationship strong enough and is he equipped to deal with these circumstances?

Perspectives on (Pre-) Registration Burden – Non-EU Exporter

- REACH compliance administration nightmare = “disproportionate burden” in WTO terms? Possible, but in meantime must deal with REACH, now – “no data, no market”
- REACH requires dedicated internal compliance coordination team (RCCT), comprising own regulatory, legal, purchasing, sales, H&S, environment and R&D personnel plus reps from each EU subsidiary concerned, ready to work together as unit for next years (SIEFs will operate to 2018, potentially longer); Management must bring this team together with clear mandate
- REACH offers one other assistance: Art 8 permits non-EU manufacturer to appoint “only representative”, to replace registration responsibility of all importers in your supply chain (related and unrelated) (importers become DUs)

Perspectives on (Pre-) Registration – Only Representative

- “Only representative” (OR) conceived to alleviate data confidentiality concerns of non-EU exporters, but potentially also major help on compliance administration
- OR becomes central EU registration point for each substance exported
 - ✓ Resolves CBI concerns with unrelated importers (avoids non-disclosure agreements)
 - ✓ Resolves multiple parties in supply chain each becoming a SIEF participant and exposed to your competitors, NGOs and other data holders
- One drawback: OR registers for cumulated tonnage of all importers (rather than each importer for its own volume only)
- Also, any EU manufacturing entity must still register for its tonnage, alongside OR – but administrative burden potentially greatly reduced overall.

Perspectives on (Pre-) Registration – Only Representative

- “Yes”, Steptoe can fulfill the “only representative” function!
(legal, regulatory, technical team to represent you in Brussels and SIEFs as appropriate)
- But, your internal RCCT still absolutely essential, with or without OR.

Conclusions / Recommendations

1. Act now to decide registration compliance strategy from structural perspective
2. Create RCCT with clear mandate
3. If Exporter + one or few related EU importers
→ RCCT alone
4. If Exporter + one or few related EU importers plus unrelated importer(s):
 - Assess data sensitivity; if not an issue then RCCT, disclose data and coordinate presence/actions in SIEF operations, but likely share technical capabilities and registration costs with unrelated importers

Conclusions / Recommendations

If data sensitivity is major concern vis-à-vis unrelated importer(s), then RCCT plus

- Non-disclosure agreements and coordination / control concerning all aspects of importer participation in SIEF data exchange activities, or
- Only Representative (CBI and efficiency purposes) to replace importers

Conclusions / Recommendations

5. Exporter + multiple EU importers (related and unrelated), RCCT plus OR may become most efficient structural solution from administration and cost perspectives, i.e., for compliance efficiency

Again: internal “REACH Compliance Coordination Team” in every scenario!!

What's next?

➤ Now that we know the structural options for (pre-) registration, what information do you actually need for pre-registration in 2008 and how do you go about compiling it?

→ Carol Mackie: “Preparation and submission of pre-registration data”