REACH Beyond Pre-Registration

Presenters:

Jim Searles

Darren Abrahams

Laura Atlee

Craig Simpson

With Guest Speaker:

Malachy Hargadon

STEPTOE & JOHNSON LLP

9 December 2008

REACH Beyond Pre-Registration

TODAY'S AGENDA

- **REACH and the European Commission**
  Presented by: Malachy Hargadon, Environmental Counselor, Delegation of the European Commission
- **Steptoe's Experience with Pre-Registration**
  Presented by: Jim Searles, Partner, Steptoe & Johnson LLP
- **You've Missed the Deadline. Now What?**
  Presented by: Darren Abrahams, Barrister, Steptoe & Johnson LLP
- **Supply Chain Communication**
  Presented by: Laura Atlee, Attorney at the New York Bar, Steptoe & Johnson LLP
- **Next Steps During the Pre-SIEF Period**
  Presented by: Craig Simpson, Solicitor, Steptoe & Johnson LLP

Moderator: Seth Goldberg, Partner, Steptoe & Johnson LLP

Malachy Hargadon

Malachy Hargadon is Environment Counselor for the Delegation of the European Commission to the United States. Prior to joining the Delegation in September 2007, Malachy served as Assistant to the Director-General of the Directorate-General for Environment in the European Commission in Brussels.

In his 14 years at the Commission, Malachy has had responsibility for liaising with the European Parliament and the EU's Council of Ministers on all aspects of transport and environment policy, and for policy coordination within the European Commission. In particular, this included the adoption of the EU's 6th Environment Action Programme in 2002.

Malachy received a Bachelor of Arts in French Studies from the London School of Economics and a Masters degree in environmental policy from the UK's Open University, and is an alumnus of the College of Europe in Bruges.

REACH
Pre-registration and beyond

Malachy Hargadon
Environment Counselor
Delegation of the EU to the U.S.

- The goals of REACH
  - Health & safety
  - Environment
  - Competitiveness

- Industry assumes greater responsibility
  - Registration
  - Risk management
  - Data and information sharing

- Pre-registration and registration
  - ECHA database
  - Deadlines
  - Manufacturers – Importers - Only representatives

Pre-registration – how did it go?

- > 2,000,000 pre-registrations
- > 100,000 substances
- 50+% during final three weeks

- 15 times more than ECHA expected

Pre-registration performance

- REACH-IT continuously upgraded
- Usage in peak hours doubled in final month – 2000 > 4000
- Back-up web-form enabled
- Some 2500 questions

Post-pre-registration

- Substances to be published by ECHA before January
- Staggered deadlines effective
- SIEF – but slight delay for pre-SIEF functionality

Post-pre-registration (II)

- Non-pre-registered: registration required for continued manufacture/import
- Late pre-registration provisions for first time substances

- Authorisation
  - Substances of very high concern (SVHCs)
  - Substitution

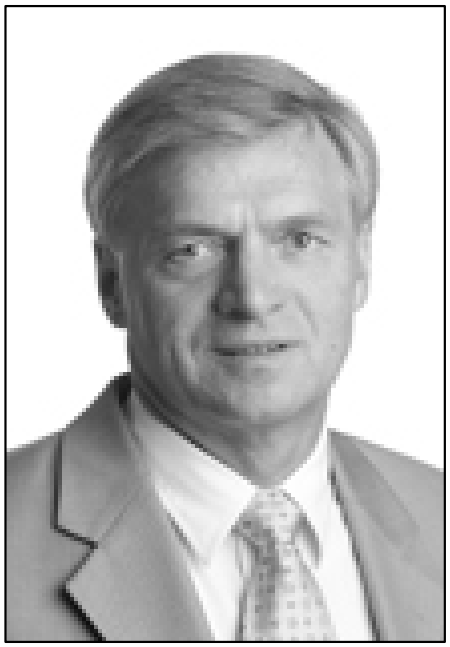
- Public consultation
  - SVHCs
  - First consultation – summer 2008
  - Hazardous properties; use and exposure; alternatives
  - Candidate list

- Commission review of Annexes I, IV, V, XI and XIII of REACH
  - Annex I: Chemical Safety Assessment / Chemical Safety Report – no amendments
  - Annex IV: Exemptions (Art 2(7)(a)) – adoption imminent
  - Annex V: Exemptions (Art 2(7)(b)) – adoption imminent
  - Annex XI: Waiving of tests – guidance available
  - Annex XIII: PBTs, vPvBs – stakeholders to comment

- European Chemicals Agency
  - Main source of information
  - Technical assistance
    - Public outreach
    - Training
    - Exchange of best practice

- REACH guidance
  - http://echa.europa.eu
  - http://echa.europa.eu/publications_en.asp

Jim Searles, jsearles@steptoe.com



Mr. Searles is a partner in Steptoe's Brussels office. His work concentrates on EU and international law, focusing on the fields of trade and environment. Mr. Searles has significant experience in substance regulation, at both Member State and EU levels. He is actively advising on the regulatory and international trade aspects of REACH, implementing Only Representative services as well as overall REACH compliance strategies. He also assists industry clients concerning EU sectoral chemical regulatory measures, climate change policy and CO2 emission initiatives. He works with companies and trade associations in the agricultural, general and specialty chemicals, automotive, information technology, steel, textiles, and general consumer goods sectors.

Steptoe's Experience with Pre-Registration

Jim Searles

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Steptoe's Experience With Pre-Registration

- Our own experience had highs and lows of a regulatory lifetime
  → IT Portal issues; late and changing/conflicting Guidance …

- 2.2 million pre-registrations indeed impressive and enormous success

- Concerned, however, that ECHA indicates that total is 15 times more than expected
  - mass pre-registrations by a few companies account for some excess
  - duplicate pre-registrations within a supply chain certainly ought to have been anticipated because many of these actually mandated by the Regulation - we made many of these precisely because of ECHA's own advisories

Steptoe's Experience With Pre-Registration

- Real fear is that <u>many pre-registrations did not take place</u> (volume should have been even higher)
  - √ Many OR enquires in just last two weeks (from US and Asia), clear that these companies would not, could not make the 1/12/08 deadline
  - √ Clients undertook extensive communications up and down supply chain and response rate has been low, meaning
    - expect that many non-EU suppliers / formulators, even large, have not responded to REACH requirements

- Note: Enforcement will come not just from national authorities, but also (and perhaps earlier/more actively) by competitors who see that a fellow producer has not pre-registered

Steptoe's Experience With Pre-Registration

➢ Duplicate pre-registrations – problem is not over; to be assessed and recommendations made/implemented

- ❖ Evident in October (still in November!) that conflicting advice being given concerning availability of certain (pre-)registration exemptions (EU chemical industry and even certain MS advice versus ECHA/Commission legal service)
- ❖ Central issue: no exemption from registration (or pre-registration) under text of Regulation unless another party has already actually "registered" the substance in question, by 1 December 2008
- ❖ Two main concerns of our clients: Re-imports and Polymers (also substances released from articles and recovered substances!)

Steptoe's Experience With Pre-Registration

Duplicate pre-registrations cont'd.

- Both re-imports and polymers raised major problem -- too close to 1/12/08 deadline, unexpected requests for disclosure of normally confidential information to be addressed too quickly

- Re-imports: (Art 2(7)(c))
  - Many non-EU producers switched to EU suppliers to be "safe" because EU producers would surely (pre-)register their substances and create exemption when these substances return to EU
  - Requirement for duplicate pre-registration of EU-sourced substances not just additional administrative burden but practical possibility to make these pre-registrations was highly challenging
    - EU producers saying "sorry, cannot disclose this information" for non-EU customer's duplicate pre-registration

Steptoe's Experience With Pre-Registration

Duplicate pre-registrations cont'd.

- Two possible solutions for duplicate pre-registration of re-imports:

  i) make the EU supplier the OR for these substances, practical (avoids supplier's CBI concerns) but non-EU formulator must provide its EU customer lists etc. to its EU supplier/OR(!), or

  ii) convince EU supplier to confidentially pass CBI to non-EU formulator's OR – this actually worked for Steptoe largely because we as the OR are also law firm and strictly bound by confidentiality rules – unsure whether this could have happened where OR is another commercial entity.

Steptoe's Experience With Pre-Registration

Duplicate pre-registrations cont'd.

- Polymers/Monomers: (Art 6(3))
  - Double blow, impacting EU and non-EU manufacturers alike, meaning "dramatic increase" of needless pre-registrations
  - Outside EU, strict interpretation of Art 6(3) negates Guidance on non-EU manufacturer's use of OR ("REACH does not distinguish between direct and indirect imports into the EU")
    - Non-EU polymer producer's OR cannot, finally, pre-register to cover quantities it sells to non-EU formulators who export to EU
    - Downstream non-EU formulators must separately arrange for pre-registrations re their (indirect) exports of the polymer --- if they can obtain the necessary information on the monomers & other bound substances; major CBI concerns again.

Steptoe's Experience With Pre-Registration

Duplicate pre-registrations cont'd.

- Where do registration exemptions stand now?
  - Commission presently examining whether "broader legal interpretation" might be found! → Mid-December decision
  - Note: "broader" interpretation appropriate but broader interpretation means many companies' urgent efforts and considerable expense to comply with the strict ECHA interpretation wasted - highlights need for "quick fix" amendments

Steptoe's Experience With Pre-Registration

Duplicate pre-registrations cont'd.

- Systemic problem: REACH does not allow for quick regulatory fixes for major implementation problems - EU obliged to follow the text strictly even if major "unnecessary" (WTO) compliance burden

- Valid points on both sides of debate but "good regulation" should have anticipated the problem and allowed upstream pre-registrations to at least *provisionally* avoid need for duplicate pre-registrations

Steptoe's Experience With Pre-Registration

- Last note on pre-registration process – it's done, for better or worse, but this was only first, comparatively easy first phase of REACH compliance
- Next steps will take us from what has been mainly an internal focus (identifying what substances we make and getting them pre-registered) to external focus – dealing with all the other pre-registrants and "sharing" mechanisms to get these substances properly registered
- But first, what if you missed pre-registration for any of your substances? – anything to do other than what ECHA advises (withdraw from market)?
- Thank you.

Darren Abrahams, dabrahams@steptoe.com

Mr. Abrahams is an English Barrister.

He is consistently recommended in EU Life Sciences by the *PLC Which Lawyer? Yearbook*, and *Legal 500 EMEA* recognises his "comprehensive understanding" of EU environmental regulation.

Recent representative matters in which he has been involved include: strategic advice on compliance with REACH; establishment of consortia and revision of agreements for REACH and in the biocides sector, defending the authorisation of plant protection products before the European Courts of Justice; data compensation negotiations for biocidal and plant protection products; drafting liability agreements for GMOs, and managing environmental liabilities associated with manufacturing processes and product sales.

What if you or your supplier missed the 1 December deadline?

Darren Abrahams

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Pre-Registration Revisited

Until 1 December:

- EU Manufacturers *(of substances/preparations even if not for EU)*
- EU Importers *(of substances/preparations)*
- Only Representatives of Non-EU Manufacturers and Non-EU Formulators *(NOT mere Distributors / Trading Companies)*
- EU Producers & EU Importers of Articles *(with substances intended to be released under normal or reasonably foreseeable conditions of use)*

could pre-register existing ("phase-in") substances.

"Late" Pre-Registration

After 1 December [Art. 28(6)]:

- ***New*** EU Manufacturers
- ***New*** EU Importers
- Only Representatives of ***New*** Non-EU Manufacturers and ***New*** Non-EU Formulators
- ***New*** EU Producers & ***New*** EU Importer of Articles (with substances intended to be released under normal or reasonably foreseeable conditions of use)

can pre-register existing ("phase-in") substances.

In order to be "New" must have gone above the one tonne or more per year threshold **for the first time after 1 December 2008**. Must submit the pre-registration within six months of first manufacturing, importing or using the substance and no later than 12 months before the relevant Registration deadline.

YOU Missed the Deadline

You are in the EU	You are outside the EU
Stop manufacturing/importing and Register! Inevitable delay, not least of all because of "inquiry process" for all potential registrants. (ECHA position)	**Stop exporting to the EU!** If you continue your EU importer (and possibly downstream) users will become legally liable e.g. Swedes will make serious offences of non-compliance criminal)
Stocks on market *before* 1 June 2008 may be used. This must be documented.	**Find an *existing* EU importer who already pre-registered for your substance in a sufficient tonnage threshold.** Document that it is acting as importer for you.
Consider creating *new* legal entity and carrying out "late" pre-registration. Company law and tax considerations.	**Find or establish yourself a *new* EU importer who can "late" pre-register.** Document that it is acting as importer for you.
	You cannot appoint an Only Representative! Reg. Gdnce (ver. 1.4) states a substance "originating from the non-EU manufacturer" must not have been "placed on the market previously" at/above 1 t/yr "after 1 June 2008".

Your SUPPLIER Missed the Deadline

You are *in* the EU **Supplier in the EU**	You are *in* the EU **Supplier Outside the EU**
Stop purchasing! If you continue you (and possibly downstream) users will become legally liable.	**Stop purchasing (importing)!** If you continue you (your importer) and possibly downstream users will become legally liable.
Find a new supplier who can certify it has been pre-registered. This if fine for most Downstream Users. However this will not work for: ➢substances intentionally released from articles ➢monomers in polymers because you can only rely on Registered (not Pre-Registered) substances! (Find a new Non-EU supplier who has not pre-registered and become a *New* EU importer of substances.)	**Find a new supplier who can certify it has been pre-registered.** However this will not work for: ➢substances intentionally released from articles ➢monomers in polymers because you can only rely on Registered (not Pre-Registered) substances! (Find a new Non-EU supplier who has not pre-registered and become a *New* EU importer of substances.)
Stocks on market *before* 1 June 2008 may be used. This must be documented.	**Stocks on market *before* 1 June 2008 may be used.** This must be documented.

Your SUPPLIER Missed the Deadline

You are *outside* the EU

Supplier in the EU

If substance <u>does not re-enter EU</u>.

No regulatory problem for You but a **commercial supply problem** – consistency of supply.

Find a new EU supplier who can certify pre-registration.

Or go to a non-EU supplier.

If substance <u>does re-enter EU</u>. Stop exporting to the EU!

(ECHA position)

Even if an EU supplier exports for re-import and did pre-register this is insufficient. **You can only rely on Registered (not Pre-Registered) substances.**

Find an *existing* EU importer who already pre-registered for your substance in a sufficient tonnage threshold or establish yourself a *new* EU importer who can "late" pre-register.

You are *outside* the EU

Supplier Outside the EU

If substance <u>does enter EU</u>. Stop exporting to the EU!

(ECHA position)

Find a non-EU supplier who can certify pre-registration via an OR. (This will not work for substances intentionally released from articles and monomers in polymers).

Find an EU *existing* importer who already pre-registered for your substance in a sufficient tonnage threshold or establish yourself a *new* EU importer who can "late" pre-register.

If substance <u>does not enter EU</u>.

No regulatory or commercial problem.

Laura Atlee, latlee@steptoe.com

Ms. Atlee is a member of the New York Bar in Steptoe's Brussels office. Her practice focuses on both EU regulatory and international law, with emphases on environment, trade, and competition law. She is acknowledged by the Legal 500 for her regulatory advice in the environmental field. Recent representative matters in which she has been involved include: advice on REACH for the metals sector and for downstream users, state aid specific to the chemicals sector, trade measures (i.e. anti-dumping and subsidies), customs, intra-EU market access, and climate change legislation.

Supply Chain Communication

Laura Atlee

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Supply Chain Communication

- REACH creates a number of new obligations that will affect communication in your supply chain.

- We will look at some of the documents you should be sending out or receiving, including:
  - √ Only-Representative appointment letters;
  - √ Safety Data Sheets; and
  - √ Information on candidate list substances in articles.

Pre-Registered Substances

- Are you sending out pre-registration confirmation letters?
  - There is no obligation to send out confirmation letters.
  - A number of approaches can be taken (e.g., mass mailing, ad hoc basis).
- If you decide to send out pre-registration confirmation letters, what do you include in the letters?
  - Mere confirmation?
  - Pre-registration number(s)?
  - Substance names?
  - EINECs numbers?

OR Appointment

- Have you notified all of your EU importers that you have appointed an Only-Representative (OR)?
  - √ Known EU importers: you should have already sent out these letters.
- What do you do if you know that your products are imported into the EU, but you do not know who the importers are?
  - √ Can you find out who the importers are?
  - √ Can your distributor help you with this obligation?

Safety Data Sheets

- When do you need to provide a safety data sheet (SDS)?

  (a) (as previously) a substance or preparation is classified as dangerous;

  (b) a substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) (criteria in REACH Annex XIII); or

  (c) a substance is included in the candidate list for a reason other than (a) or (b) above.

Safety Data Sheets

- When do you need to provide a safety data sheet (SDS)?
  - A recipient of a preparation can request an SDS if the preparation contains:

    (a) 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;

    (b) 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 candidate list for authorisation) or

    (c) A substance for which there are Community workplace exposure limits.

Safety Data Sheets

- What language must your SDS be written in?

  - A safety data sheet must be supplied in the official languages of the Member States in which the substance or preparation is placed on the market.

    - Unless the Member State(s) concerned provide otherwise (Art. 31(5))

Substances of Very High Concern

- You have a substance on the candidate list in your article.
  - √ In addition to possible notification requirements, you need to supply certain information now.
  - √ Industrial or professional user, or distributor versus consumers
  - √ In all cases the information must be sufficient to enable safe use of the article, including (as a minimum) the name of that substance.

SVHC information requirement 0.1% concentration weight by weight of article (not each component)

Dissenting view: Austria, Belgium, Denmark, France, Germany & Sweden

Product De-selection

- You are concerned about your product staying on the market.
  - √ Candidate List
  - √ Registry of Intention
  - √ The International Chemical Secretariat, with the assistance of a number of non-governmental organisations published its ("SIN") list, which contains more than 200 hazardous substances that they believe should be added to the Candidate List.

Additional Considerations

- How do you fit REACH compliance obligations into your supply chain?

  - √ Imposing obligations on others versus having obligations imposed on you:

    - Supply contracts:
      - Annual negotiations
      - Amendments to the contracts
    - Purchase Orders
      - Who drafted the provision?

  - * Are the obligations inadequate or overbearing?

Craig Simpson, csimpson@steptoe.com

Mr. Simpson is an English solicitor in Steptoe's Brussels office. His practice is focused on chemicals registration and authorisation under REACH, biocides, pesticides, pharmaceuticals, and medical devices. Recent experience has included representing a biotechnology company and a major trade association as interested third parties in high profile litigation before the European Courts of Justice and preparing Task Force and Data Sharing Agreements for collective dossier notification under the Biocidal Products Directive. Mr. Simpson is consistently recommended in PLC's Life Sciences Handbook.

What Now?

Next Steps During The Pre-SIEF Period

Craig Simpson

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Pre-SIEF and the REACH IT Webpage

- What is the Pre-SIEF?
  - Between end of pre-registration window (December 1) and pre-SIEF participants' agreement on substance sameness (= formation of SIEF).
- Info on The REACH IT webpage
  - 'Pre-SIEF partnership' list of other pre-registrants for same substance
  - Own pre-registration appears first
  - SIEF Formation Facilitator (SFF), if any, second
  - 'A' = active, 'I' = inactive (deactivated), 'F' = volunteered SFF
- IT delay
  - ECHA IT spanner in the works - whole list not visible until January
  - progress on sameness discussions significantly held up

Types of Pre-SIEF Participants and Prioritisation Criteria

- Different types of pre-SIEF participants:
  - Main suppliers
  - Users of substances
  - Strategists/the great unknown (those whose identity hidden by OR or third party)
- Prioritising actions for pre-registered substances
  - Limited resources
  - Key substances commercially
  - Highest volumes sold in/to the EU (especially over 1000 tonnes) or dangerous substances (earlier registration deadlines)

Position for Each Substance

- Strategy will determine desired position in pre-SIEF
- Two extremes:
  - key supplier volunteers as SFF (control, wants election as lead registrant)
  - small formulator (relying on supplier's registration) wanting to avoid costs and registration
    - should check supplier on list and deactivate (i.e. not a registrant) as soon as possible

Agreement on SFF

- SFF
  - ‘F’ on list does not equal right to be SFF
  - ‘F’ = first pre-registrant to volunteer as SFF
  - competitors for SFF position or if participants want different SFF – probably ‘F’ to initiate vote (no guidance)
  - pressure on biggest player to act if no volunteer

Sameness Issues

- Sameness (is hazard data sufficiently similar to be part of the same joint registration?)
  - already advanced or even completed?
- SFF key to sameness discussions
  - suggest dedicated website or other IT tool (other than the REACH IT portal)?
  - leads to birth of SIEF
- Pre-SIEF participants not all pre-registered same substance?
  - does not invalidate pre-registration of 'odd' pre-registrants
  - question is which pre-SIEF does that pre-registration properly belong to?

Sameness Issues

- Options for 'odd ones out' – 2 scenarios:
  - Only one member pre-registered different substance
    - seek info from ECHA on appropriate pre-SIEF/SIEF and identity of SFF or Lead Registrant; and/or
    - check 1.1.09 list for similar substances.
  - Group who have pre-registered different substance
    - possibility for 2 separate SIEFs to emerge from that pre-SIEF group
- Can have different classifications for the same substance

Sameness Issues

- Sameness confidentiality agreement necessary where
  - √ Substance distinction on basis of impurity and consequent disclosure of manufacturing process
  - √ composition and/or raw materials disclosed
- SFF, or effected participants, to suggest

Immediate Data Audit

- Internal data audit now! (quality, relevance and value)
  - even ‘deactivators’ need to be ready to respond to data requests
  - more efficient if centralised via SFF/lead registrant (short one month response limits = must be ready before)
- Key audit questions
  - which studies worth seeking recompense for?
    - will costs of negotiation outweigh the compensation recovered?
    - agree Klimisch 1 and 2 cats only?
  - orphan studies - not clear who owns?

Reviewing Existing Consortia

- If know (pre pre-SIEF) consortia exist:
  - √ contact consortia or trade association and obtain and review agreements

- Late entry fees
  - √ justified, transparent reflection of founding members sweat equity?; or
  - √ is fee excessive/discriminatory?

Reviewing Existing Consortia

- Costs sharing
  - where specified, is it acceptable to your specific circumstances?
    - for example, an equal shares versus volume based criterion
  - not required to pay for studies before you actually require them for registration deadline (even though may agree to data/costs sharing well before)
- Ensure antitrust policy and adequate confidentiality provisions

No Existing Consortia Known

- Double-check
  - Ask other per-SIEF participants
  - Consult unofficial lists

- Consider setting up consortium
  - Many possible models
  - All participants members, or only a few (for example, SFF/lead registrant and main data holders)?
  - Time limit for 2010 substances! Decide essential structures (steering committee, consultant) for data review, rest tbc later

Steptoe REACH Services

For additional information, please contact a member of the REACH services team:

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