REACH Pre-registration: Preparation & Execution Webcast

When Experience Matters®

STEPTOE & JOHNSON LLP

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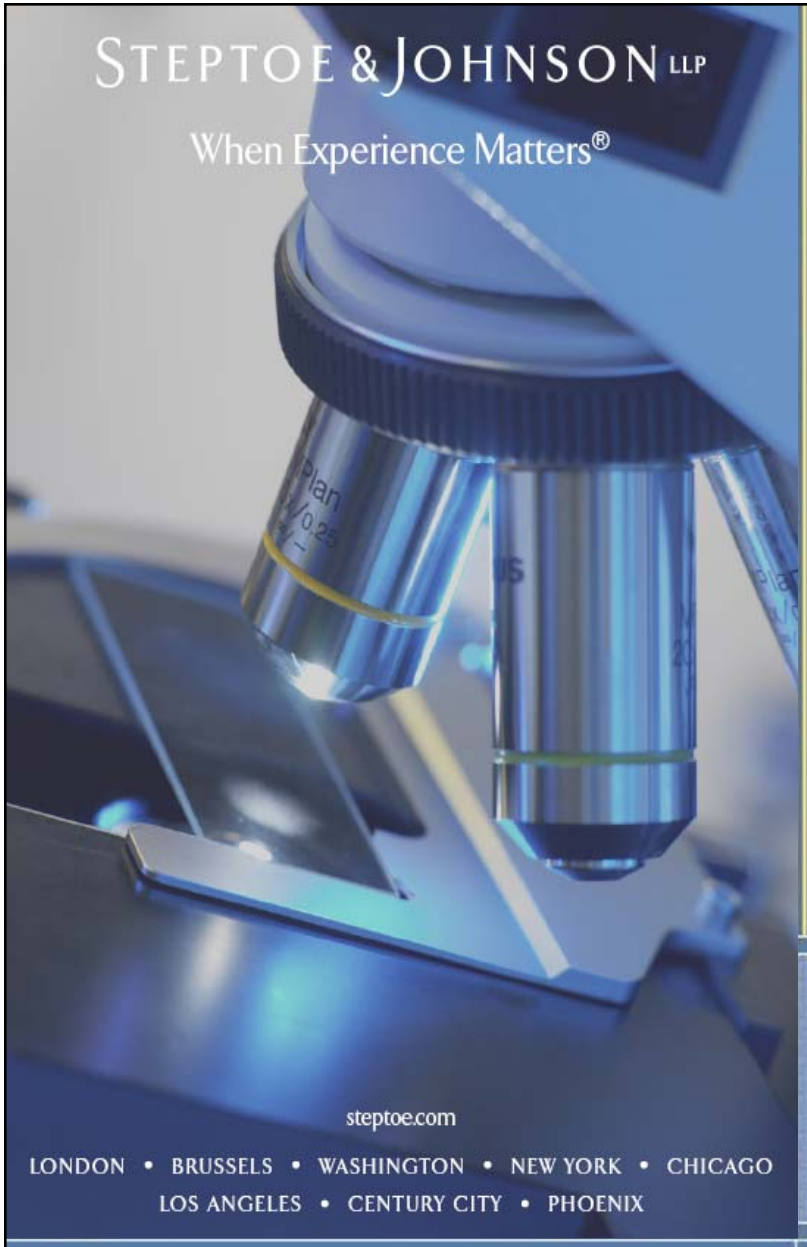
23 October 2007

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.



CONSORTIA: WHAT, WHY, WHEN AND HOW?

Craig Simpson, Attorney

"REACH Pre-Registration Webcast"
23 October, 2007

STEPTOE & JOHNSON LLP

CONSORTIA: WHAT IS A CONSORTIUM? DISTINGUISH FROM SIEF

- What SIEF is not:
  - ✓ A SIEF is not a consortium/ task force (industry confusion)
- Aspects of SIEF which differ from consortia:
  - ✓ Membership, and obligations to request and give data, mandatory for pre-registrants
  - ✓ set up by Agency, not by members
  - ✓ motivated principally by public sector interests (avoidance of unnecessary animal testing)
- Consortia:
  - ✓ Voluntary
  - ✓ Motivated by mutual benefit of Members

CONSORTIA: NOT MANDATORY

- No obligation under REACH to form or join a consortium
- Form of mandatory cooperation (data sharing, classification and labelling, joint submission of data towards registration ('OSOR'), election of lead participant and lead registrant) not specified
- Different options for cooperation between potential registrants of same substance:
  - ✓ Virtual communication forum with no binding rules
  - ✓ *Ad hoc* email communications between potential registrants construed as contractual terms
  - ✓ Bilateral agreements between data owner and data purchaser
  - ✓ Pre-consortium agreement with confidentiality agreement
  - ✓ Consortium agreement

CONSORTIA: WHY CONSORTIA?

- Why choose consortia instead of alternative cooperation vehicles?
  - ✓ Preference for formalised relationship and binding rules ('safer' re confidentiality, anti-trust concerns)
  - ✓ Dedicated structure the only time and resource efficient way to cooperate in mandatory (and non-mandatory) areas
  - ✓ Experience of BPD Task Force Agreements
  - ✓ Multilateral cooperation necessary to share costs of purchasing existing data
  - ✓ increased ability to influence competitors' approaches to data-gap filling and registration

CONSORTIA: WHY CONSORTIA?

- ✓ stronger position v. ECA (including appeals)
- ✓ smaller companies may prefer to lean on major M/I's who take lead
- ✓ pressure from DUs on their suppliers to join consortia (to ensure listing of their 'identified use')

➢ Main disadvantage: Time and costs of setting up and/or participating in consortia

CONSORTIA: PURPOSE AND TIMING (WHY AND WHEN?)

- When to form a consortium depends on why formed
- No obvious advantage to early consortium membership *per se*
- Reasons and timing for pre-SIEF consortium formation

N.B.: Cooperation under REACH starts before the SIEF!

- ✓ Checking 'sameness' with others pre-registering under same substance identifier: post pre-registration but pre-SIEF; initiative of 'SIEF Formation Facilitator'?
- ✓ Sufficient time to set up consortium? Transitional period for M/I's of substance quantities > 1,000 tonnes per year ends 1.12.2010 ('no date no market' begins): start early as possible

CONSORTIA: PURPOSE AND TIMING (WHY AND WHEN?)

- Variations in post-SIEF consortium formation
  - ✓ One consortium incorporating all SIEF members
  - ✓ Two or more consortia sharing data between them in on SIEF: for example, where different classifications for same substance with different purity profiles or using different processes
  - ✓ One consortium, with independent parties (for example pure data holders) outside
  - ✓ Exchange of existing data, development of new data and cooperation at registration stage? Or only some?
  - ✓ Covering 'family' of substances, so active on a number of different SIEFs
  - ✓ Consortia in different SIEFs exchange data for read across purposes

CONSORTIA: HOW? WHAT YOUR CONSORTIUM AGREEMENT SHOULD COVER?

- Citation rights only
- Confidentiality provisions:
  - ✓ Restrict access to certain staff (under confidentiality agreement)
  - ✓ Provisions to deal with breach of confidentiality by data users or if legally required to disclose
- Data compensation provisions
  - ✓ 'provide proof of cost' - historic value or current value ('replacement value') of studies?
  - ✓ Regulation 'equal shares' default mechanism - risk premium?
  - ✓ Costs mechanism flexibility for later purchases of data?
  - ✓ 'Set off' compensation for holder of studies similar to key study chosen for submission

CONSORTIA: HOW? WHAT YOUR CONSORTIUM AGREEMENT SHOULD COVER?

- Task force activity/ running Costs
- Establish structure and composition: Executive and Technical Committee, Secretariat/ Day to Day Management, Decision making/ voting rules
- Late Entrant Fees – no freeriding on administration costs
- Joint ownership rights (IP) in new jointly developed data and their protection
- Communication with other consortia or individuals

CONSORTIA: HOW? WHAT YOUR CONSORTIUM AGREEMENT SHOULD COVER?

- When it goes wrong: default and withdrawal of participants, dispute resolution, liability to third parties or between consortium members
- Mechanisms for mandatory cooperation obligations: data sharing (and purchase from outside consortium), data development, classification and labelling, etc.
- Mechanisms for appeal of ECA Decisions
- Antitrust provisions – measures to avoid discrimination or the exchange of commercially sensitive information

CONSORTIA: AVOIDING EC COMPETITION LAW INFRINGEMENT

- Issue 1: Consortium potential cloak for a cartel – exchange of commercially sensitive information between competitors
- Example of commercially sensitive information
  - ✓ Margins, profits, discounts or prices charged to customers/ end users;
  - ✓ Names of customers or customer-specific translation information;
  - ✓ Key terms and conditions for sales;
  - ✓ Future strategic, business or investment plans;
  - ✓ Current market shares and sales volumes;
  - ✓ Suppliers and input costs for key materials.

CONSORTIA: AVOIDING EC COMPETITION LAW INFRINGEMENT

- Adherence to Antitrust Policy. All consortium/ task force members to:
  - ✓ Presence of lawyer/ compliance officer to 'wave red flag';
  - ✓ Acknowledge Antitrust Policy before Task Force meeting;
  - ✓ Limit all discussions during meetings to agenda topics;
  - ✓ Protest immediately if discussion becomes sensitive;
  - ✓ Maintain minutes of all meetings
- Incorporate Antitrust policy clause preventing members from exchanging market information
- Use independent third party to collect sensitive data

CONSORTIA: AVOIDING EC COMPETITION LAW INFRINGEMENT

- Issue 2: Avoid Discriminatory Behaviour
  - ✓ Grounds for refusal of entry to consortium must be objectively justifiable and consistent
  - ✓ Entry fees must not be extortionate
  - ✓ Data purchasers should not pay different amounts for the same data without good reason
- Issue 3: Bundling of Data
  - ✓ Data owner cannot make sale of required data conditional on other data
  - ✓ Competition law offence of tying/ bundling
  - ✓ Breach of Regulation: 'Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements' (Article 30(1))

CONCLUSIONS

- There is no obligation under REACH to join a consortium, only to cooperate with competitors in certain areas.
- A consortium is distinct from the concept of a SIEF.
- Potential registrants may strategically favour forming consortia for a number of reasons – for example, efficiency, more solid ('safer') protection of interests.
- When to form a consortium depends on the stage of the REACH timetable at which potential registrants wish to cooperate. For example, cooperation on sameness check would require a pre-SIEF consortium.

CONCLUSIONS

- There are a range of different scenarios for consortium formation – for example, variations in the numbers of consortia for the same substance, or in the number of substances covered.
- Suitable provisions for a consortium agreement will vary according to its purpose (seek legal advice!).
- Particular concerns when drafting agreement should be protection of CBI and avoiding infringement of EC competition law.

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, as well as developing 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, chemicals, motor vehicle, information technology, steel, textiles, and general consumer goods sectors.

REACH and the "Only Representative"

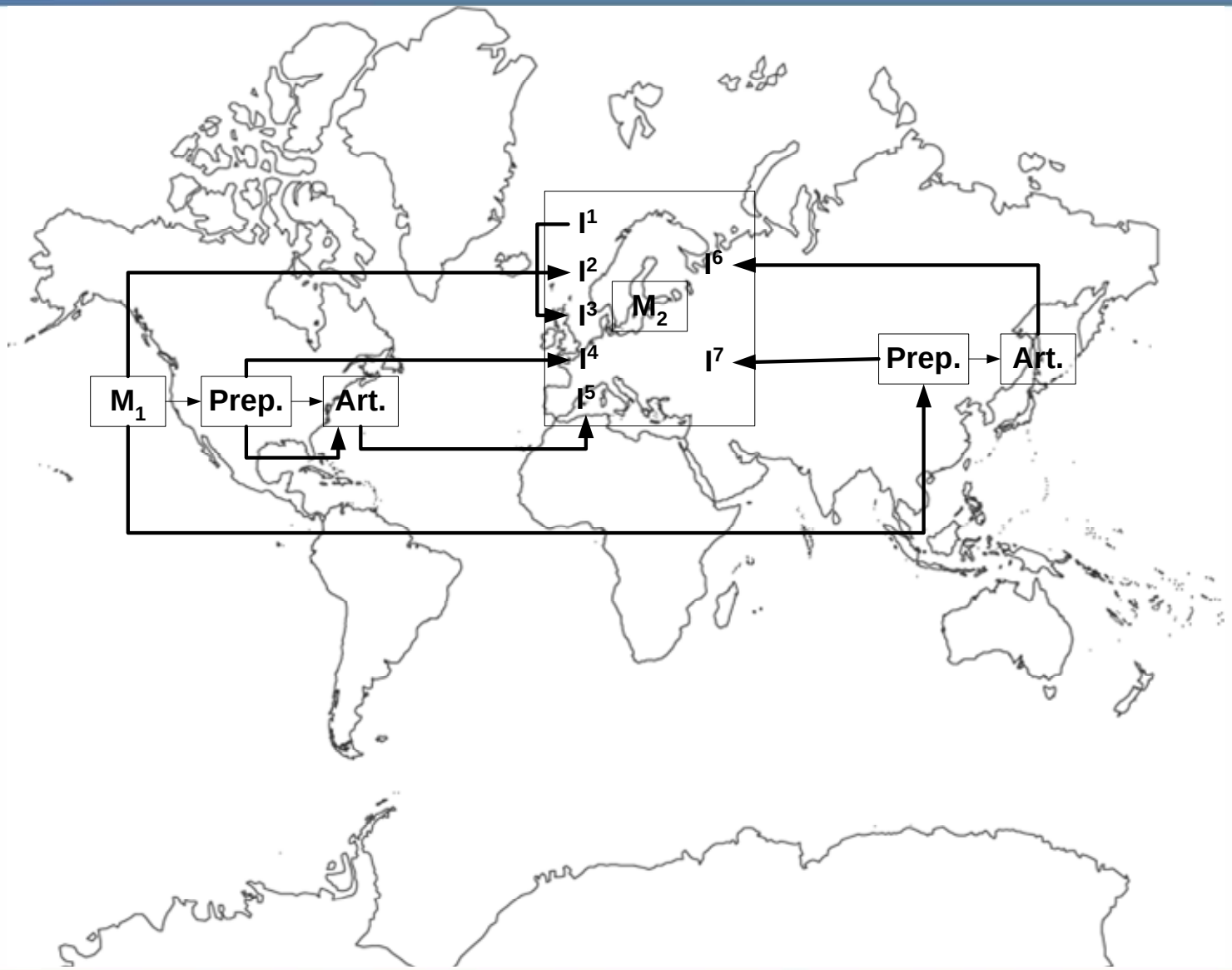
Steptoe Webcast Presentation

23 October 2007

JAMES SEARLES
Partner

STEPTOE & JOHNSON LLP

Commercial Considerations – Supply Chain



I. Commercial Considerations

- Non-EU Manufacturers ("NEUMs") do not have direct REACH compliance obligations, but…

  NEUM's substances face REACH "no data, no market" principle. If substances are not properly registered, NEUM liable to substantial damage or loss of EU market (i.e., disrupt existing supply chain) as well as fines under national law

- NEUM has to get compliance right; no one else can fully take care of it without you. (Competitors will enjoy your predicament!)

- 2 Options: Either registration is done by EU importer(s) or, alternatively, NEUM may be represented by a natural or legal person located in the EU territory, an "Only Representative"

- What's involved in assessing which option to choose?
  - ✓ Protection of CBI (Confidential Business Information)
  - ✓ Registration efficiencies (costs, administrative burden)
  - ✓ Professional diligence

Commercial Considerations

NEUM choices:

a) Importer(s) registration option

- ✓ Importer(s) may prefer to switch to EU supplier rather than take on REACH compliance obligations, so NEUM must "facilitate"
- ✓ NEUM must provide CBI and other registration **data** to each importer (direct and indirect, related and unrelated) for use in its individual registration and SIEF/consortium activities
  - Seek to ensure protection of NEUM's CBI (risk factor if independent importer also acting as Registrant for imports from other NEUMs/ competitors)
- ✓ NEUM likely must **finance** some/all of each importer's registration costs (registration fees, any required SIEF data-sharing costs, related consultant/legal fees, potential consortium costs distinct from SIEF activities)

Commercial Considerations

b) Alternative Registration option - Designate and provide data to trusted "only representative" ("OR") who substitutes importer(s) registration and other REACH obligations

OR can be:

- related importer/subsidiary (if any)
- EU manufacturing unit (if any)
- new EU office set up for this role
- the most trusted of unrelated importers
- external consultant who is experienced (technical and legal support)

= trust relationship to handle REACH and assume any liabilities

** NEUM must still provide own data to OR under CBI protection conditions to (pre-)register and actively represent NEUM in SIEF/consortium activities

II. LEGAL Framework

Article 8

Only representative of a non-Community manufacturer

1. A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfill, as his only representative, the obligations on importers under this Title.
2. The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.
3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.

LEGAL Framework – in brief

Only Representatives are natural or legal persons appointed by non-EU Manufacturers to fulfill the obligations of Importers.

Only natural or legal persons:

(i) established in the EU and,

(ii) having "sufficient background" in the practical handling of substances and the information related to them,

may be appointed.

ECHA commentary / interpretation

Not just the substance manufacturer outside the Community can appoint an only representative: Anyone who

- Manufactures a substance on its own, in preparations or in articles,
- Formulates a preparation or
- Produces an article that is imported into the Community.

It is not necessary to directly export the substance, preparation or article to the Community; a supply chain may exist outside the Community before import takes place.

Importer becomes a downstream user only for those substances that have been registered by an only representative. Importer will still have to register imports of same substance from other suppliers who do not appoint an OR.

External NEUM Concerns:

- When OR is appointed, NEUM must formally mandate OR (contract) and inform all Importer(s) within the supply chain.
- Importer(s) becomes Downstream User and must comply with DU information obligations – make sure all downstream uses notified to OR!
- OR then takes up (pre-)registration obligations (and participates in phase-in Substance Information Exchange Forum (SIEF))
- Upon registration, OR must submit (a) copy of NEUM mandate officially assigning him as "only representative".

Practical Implications of OR Appointment

- OR registers full volume of substance exported to EU by this NEUM (potential higher tonnage band/data requirements vs. individual importers, but balance overall efficiencies)
- OR also to keep available and update information on quantities imported and customers sold to (including their uses), as well as information to communicate down the supply chain.
- An Only Representative can represent several non-EU manufacturers of a substance.

Practical Implications of OR Appointment

Internal NEUM concerns:

- OR is legally responsible for registration. Nevertheless, in most cases NEUM has to provide OR with data necessary for registration, and funding.
- Any EU manufacturing unit of NEUM still has to register its tonnage
- If the NEUM decides to change his OR, new OR should, in agreement with former OR, update the registration dossier (change registrant identity) and assume all OR responsibilities thereafter.
- NEUM is not off the REACH hook: internal REACH compliance coordination team and close cooperation with OR's registration process still important.

IV. SIEF Concerns for OR (as opposed to consortium issues)

Pre-Registration Activities relating to SIEF (context of legally binding rules relating to substance registration) “Potential Registrants” =

- Manufacturers and Importers of phase-in substances having pre-registered that substance.
- Producers and Importers of articles having pre-registered that phase-in substance if intended to be released from articles.
- Only Representatives of non-EU Manufacturers having pre-registered that phase-in substance.

OR SIEF Concerns

- The Potential Registrants have to agree on:
  - who will be the Lead Registrant;
  - the information to be jointly submitted
  - classification & labeling
- Lead Registrant: one substance = one SIEF = one joint submission = one Lead Registrant) even if several tonnage bands co-exist.
- All Manufacturers, Importers and Only Representatives concerned by a substance (independently of the tonnage band) should participate to the discussion as soon as possible and agree on a Lead Registrant and the information to submit jointly.

OR SIEF Concerns

- Note: "joint submission of data" (Art 11) does not eliminate obligation for each registrant (manufacturer, importer or OR) to submit individual registration dossier.

- OR to individually provide information required under Article 10 except (1) studies and proposals for testing (if data gaps), (2) classification and labeling information, and (3) CSR and/or the guidance on safe use if NEUM/OR agrees to submit these jointly (opt out possible).

OR SIEF Concerns

OR not to be confused with "Third Party Representative“ (TPR) (Art 4)

- TPR can be appointed if any manufacturer/importer prefers not to disclose its interest in a particular substance (this may give indications to competitors about production or commercial secrets).
- TPR must be indicated at pre-registration because contact details given in pre-registration will be made available to all Potential Registrants of the substance(s) pre-registered under the same identity code as well as to Potential Registrants of all other substances for which read-across possibilities have been indicated
- Legal entity nominating a Third Party Representative retains the full legal responsibility for complying with registration and other obligations under REACH. TPR merely acts as an “agent” for the manufacturer/importer who remains anonymous vis-à-vis the other members of the SIEF
- In some cases an OR (e.g., when a subsidiary of NEUM) might also appoint TPR, for same confidentiality reasons

V. OR and Consortium Involvement

Consortium membership (for SIEF purposes) does not necessarily coincide exactly with SIEF participants.

Categories of participants who may be interested to be members of a consortium/co-operation agreement (not exhaustive):

(A) Categories strictly deriving from a SIEF:

- Manufacturer(s);
- Importer(s);
- Only Representative(s);
- Data owner(s) who are willing to share data: for example laboratories, organisations, consultants, trade/industry associations or downstream user(s) if they have relevant information, for example study data and exposure data.

OR and Consortium Involvement

(B) Other categories may also be considered:

- Other downstream user(s) (not data holders);
- Third Parties providing services and assistance to a consortium such as trade/industry associations, sectoral associations, service providers, and law firms;
- Non-EU manufacturer(s) who are also willing to participate directly, and not only through their EU-Only Representative, although not being entitled to register directly;
- Potential Manufacturers and Importers which under Art 28.6 could be Potential Registrants (future first-time producers/importers >1 tonne after 2008);

Concerns Relating to OR Data-Sharing

- Competition/cartel concerns relating to OR information exchange in SIEF or Consortium
- Exchange of data on terms pre-agreed with NEUM (what data, at what cost)
- Compensation of data-sharing costs
- OR liability to NEUM for unauthorised actions, esp. re disclosure of data
- Liability to third parties – to be negotiated with NEUM

Conclusions –

- Only Representative can offer greater efficiency (cost savings) in achieving registration of substances, especially where multiple importers including unrelated importers who would otherwise each have to register
- OR can reduce risks relating to improper disclosure of CBI during the registration process
- OR will monitor, provide on-going focus and expertise and protect NEUM interests in official and related compliance activities (e.g., pre-SIEF and SIEF activities, related association/consortium activities)
- OR can bring expertise also to any REACH authorisation process concerning SVHC.

REACH and the “Only Representative”

- Thank you!
- Questions?

Jim Searles
Steptoe & Johnson LLP
Av Louise, 240
1050 Brussels
jsearles@steptoe.com
+32 (O2) 626 0500, +32 (0) 475 345 807

Darren Abrahams, dabrahams@steptoe.com

Mr. Abrahams is an English Barrister in Steptoe's Brussels office. His practice is focused on EU regulatory requirements and related commercial issues in the chemical regulatory and life sciences area. He is a consistently recommended practitioner in the PLC's Life Sciences Handbook and is acknowledged by the Legal 500 for his regulatory advice in the environmental field. Recent representative matters in which he has been involved include: defending the authorisation of plant protection products before the European Courts of Justice; strategic advice on compliance with REACH; protecting data, establishing consortia, and drafting supply agreements and letters of access for biocidal products; and managing environmental liabilities associated with manufacturing processes and product sales.

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.

What REACH does not tell you.

Steptoe Webcast

23 October 2007

DARREN ABRAHAMS
Barrister
&
LAURA ATLEE
Attorney

STEPTOE & JOHNSON LLP

OVERVIEW

- **REACH Regulation has substantial gaps.**
- **REACH non-legally binding Guidance aims to fill these.**

however….

- **Conflicts between Guidance & Regulation.**
- **Entirely new elements which Guidance adds.**
- **Pending pipeline of import Guidance.**

SIEFS

- **"SIEF formation facilitator" / Lead Registrant - what's the difference?**
- **"Super User" - a parent's responsibilities.**
- **"Like" Substances - it's up to you!**

BIOCIDES & PPPS

Clear conflict between guidance and Regulation on calculation of tonnages.

BIOCIDES

"Active substances manufactured or imported for use in biocidal products only …"

Article 15(2)

PPPs

"Active substances and co-formulants manufactured or imported for use in plant protection products only …"

Article 15 (1)

1. **"Only" totally excludes from the Registration exemption any substance which has a *dual use* (i.e. no splitting of tonnages allowed) BUT Guidance completely ignores this.**
2. **This exposes Registrations to potential legal challenge from competitors and hostile States.**
3. **Even when exemption applies - participation in SIEF still mandatory (Art. 29) which risks data seepage unless closely monitored.**

ARTICLES

- **Calculation of tonnage - register all not just what is to be released.**
- **0.1% applies to whole article not components or homogenous parts.**
- **Container *v* Article: Indicative criteria.**

POLYMERS

Polymers currently exempted from REACH Registration but Registration required for monomer substance(s) or any other substance(s) of polymers that have not already been registered by an actor up the *supply chain* if conditions in Article 6(3) met (2% by weight and >1t/a)

Under REACH the reacted form of a monomer ("a monomer unit") in a polymer must be registered even though it is no longer exists in the polymer as an individual substance.

Recent reference to ECJ on validity of Article 6(3)*

* SPCM Sa, Lake Chemicals & Minerals, C.H. Erbslöh and Hercules (R on the application of) *v* Secretary of State for the Environment Food & Rural Affairs) CO/4370/2007

EXEMPTIONS

Review of exemptions:

- **Annexes IV: limited consultation**
- **Annex V: internal review**

DATA PROTECTION & COMPETITION

Data Sharing Guidance formalises notion of "Independent Third Party" or "Trustee" to:

- produce aggregate anonymous figures
- calculate cost allocation based on individual figures for cost sharing
- send individual sensitive information to authorities without circulating to other actors

Can be performed by a legal or natural person not directly or indirectly linked to a manufacturer/importer or their representatives e.g. consultant, law firm, laboratory, European/international organisation etc.

TERRITORIAL SCOPE

EEA Joint Committee Decision pending to bring:

- **Norway**
- **Iceland**
- **Lichtenstein**

within REACH regime (treated as EU entities).

NB: Swiss-based entities remains non-EU.

PENALTIES

In absence of pre-registration of phase-in substances the full Registration obligation applies as of 1 June 2008 to:

- **New substances**
- **Non-preregistered phase-in substances**

and penalties may be applied if failure to do so from 1 June until marketing is suspended.

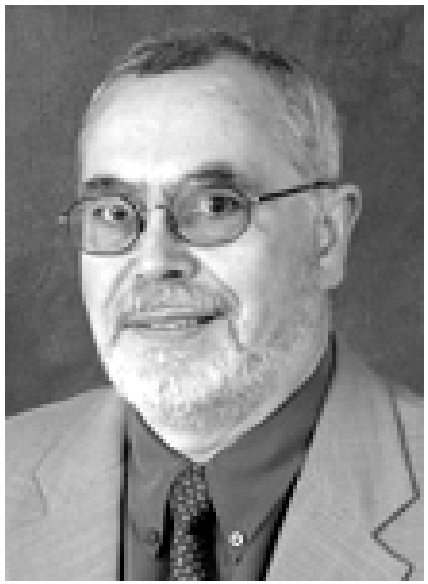
Underlines strategic importance of pre-registration (especially for articles).

QUESTIONS?

dabrahams@steptoe.com
latlee@steptoe.com

STEPTOE & JOHNSON LLP

Graham Lloyd, glloyd@regs.co.uk



Mr. Lloyd is a regulatory consultant with more than 25 years experience in European regulation of the chemical industry; he works directly on a broad range of EU, UK, and other national regulatory programs. Mr. Lloyd counsels clients in all aspects of chemical regulatory affairs, from ensuring compliance with the many EU directives and regulations applicable to the chemical industry, to comprehensive monitoring and analysis of emerging regulatory initiatives. In addition, he is widely recognized for his leading role in the industry response to the Biocidal Products Directive.

IDENTIFICATION AND NAMING OF SUBSTANCES UNDER REACH

Graham Lloyd. Consultant

STEPTOE&JOHNSON LLP

steptoe.com

23 October 2007

What is a 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."

Key definitions

- **Component** - Substance intentionally added to form a preparation.
- **Constituent** -Any single species present in a substance that can be characterised by its unique chemical identity
- **Impurity** - An un-intended constituent present in a substance as produced.
- **Additive** - A substance that has been intentionally added to stabilise the substance

Guidance Document - RIP 3.10

"for Identification and Naming of Substances under REACH" ECHA – June 2007

- Provides guidance to manufacturers and importers on the recording of the correct substance identity
- It is essential for the smooth operation of REACH to understand, characterize and correctly identify substances you believe to be covered by REACH
- This using recognized identifiers e.g. EINECS/CAS numbers.

Previous problems

Problems highlighted:

- One substance with several EINECS numbers
- One EINECS number covers several substances
- Substances with No EINECS or CAS numbers

Caused additional work for the authorities

Substance pre-registered under the wrong EINECS entry

In the pre-registration period – re-submit & withdraw the wrong one.

After Dec 1st 2008 – "refinements" can be made, i.e. move to a SIEF for a substance with a similar structure

BUT cannot move to a SIEF of an unrelated Substance.

Several EINECS entries for same substance

During pre-registration make a submission for all EINECS entries

Post pre-registration - agree correct positioning & withdraw unwanted entries or allow to remain Dormant.

Multiple SIEF's, in operation, check early, it can be important when wanting to use the read across facility.

EINECS entries cover more than one substance

Can be incorrect or broadly defined EINECS entries.

Participants to exchange and examine chemical specifications.

To determine if data sharing is possible.

Can lead to the formation of several separate SIEFS.

Substances with no EINECS/CAS number

Using the names of the substances and available guidelines, clarify their identity and composition.

Substances can then be regarded as the same

Formation of a SIEF

Joint submission and data sharing

Pre-registration (*Article 28)*

Objective - to bring together potential registrants of the same substance, at this stage not essential to provide full Identification of substances.

The registrants

- To submit a limited amount of data on each substance.

The Agency

- To produce a list of substances to facilitate the formation of SIEF's.

Registrants form SIEF's

- They will then need to establish "sameness" of the substances

After the formation of a SIEF

Substance identification is to be performed in line with REACH. The identifiers to be used are:

- IUPAC names
- CAS numbers
- EC numbers
- Molecular and structural formulae
- Chemical composition

These should cover almost all substances

Substances divided into 2 main groups

- **Well defined substances**
  - Mono constituent substances.
  - Multi constituent substances.
- **Not well defined**
  - Substances of Unknown or Variable Composition, complex reaction products or Biological materials (UVCB)

Mono constituent substances

Identification is by chemical names and identifiers

- Main constituent is present at ≥ 80%
- Impurities present at ≥ 1.0% should be specified by the chemical name and/or Cas number and/or molecular formula
- Hazardous impurities (PBT) must always be specified

Multi constituent substances

Contain more than one main constituent

- Concentration can vary, 10 - 80%
- They result from chemical reactions (they are not preparations)
- Must register the substance as it is produced

Identifiers used:

- Chemical name, qualitative and quantitative composition.
- Impurities to be specified

Examples

Mono constituent substances

Main constituent: m-xylene. 91.0%

- Impurity o-xylene. 5.0%

Multi-constituent substances

Main constituents

- A m-xylene 50%
- B o-xylene 45%
- Impurity p-xylene 5.0%

Substances of Unknown or Variable Composition complex reaction products or Biological materials (UVCB)

Biological substances

- Plant or animal species
- Part of plant/organ of known or generic composition.
- Chromatographic and other fingerprints

Chemical and mineral substances with poorly defined, complex or variable composition (UVC)

- Known or generic composition
- Chromatographic and other fingerprints
- Reference to a standard index

UVCB - Examples

- **Biological materials**
  - Extracts from plants - fragrances
  - Complex macromolecules - enzymes
  - Fermentation products - antibiotics
- **Chemical & mineral substances**
  - Fractions & distillates - tars
  - Minerals - slags

Naming of UVCB substances

In most cases the naming of a UVCB substance will be in the order of source followed by process.

- Biological sources are identified by the name of the species. (*S. cerevisiae)*
- Non-biological sources are identified by the starting materials used. *(Phosphate ores)*
- Processes are identified by the type of chemical reaction, synthesis or as refinement step e.g. extraction. *(Linseed oil, epoxidised, reaction product with tetraethylenepentamine)*

Chemical "sameness"

Important when considering data sharing

Mono constituent substances

No differentiation made between pure and technical grades

Where impurity profiles differ markedly

- it will require expert judgment to determine if data on a such a substance can be used for the registration of others in the SIEF

Chemical "sameness"

Hydrates and anhydrous considered the same

Acids or bases and their salts are regarded as different, e.g. sodium and potassium salts

Branched or linear chains regarded as different

For multi-constituent substances requires the registration of the manufactured substance

Conclusions

Review all substances to determine:

- They are covered by REACH
- Which identifiers are used
- Are the identifiers correct
- Which other substances are sufficiently similar to allow the sharing of data

Thank You

- To obtain copies of the presentations:
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