



STRATEGIES FOR PRE-REGISTRATION *AN EU / US PERSPECTIVE*

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STEPTOE & JOHNSON ^{LLP}

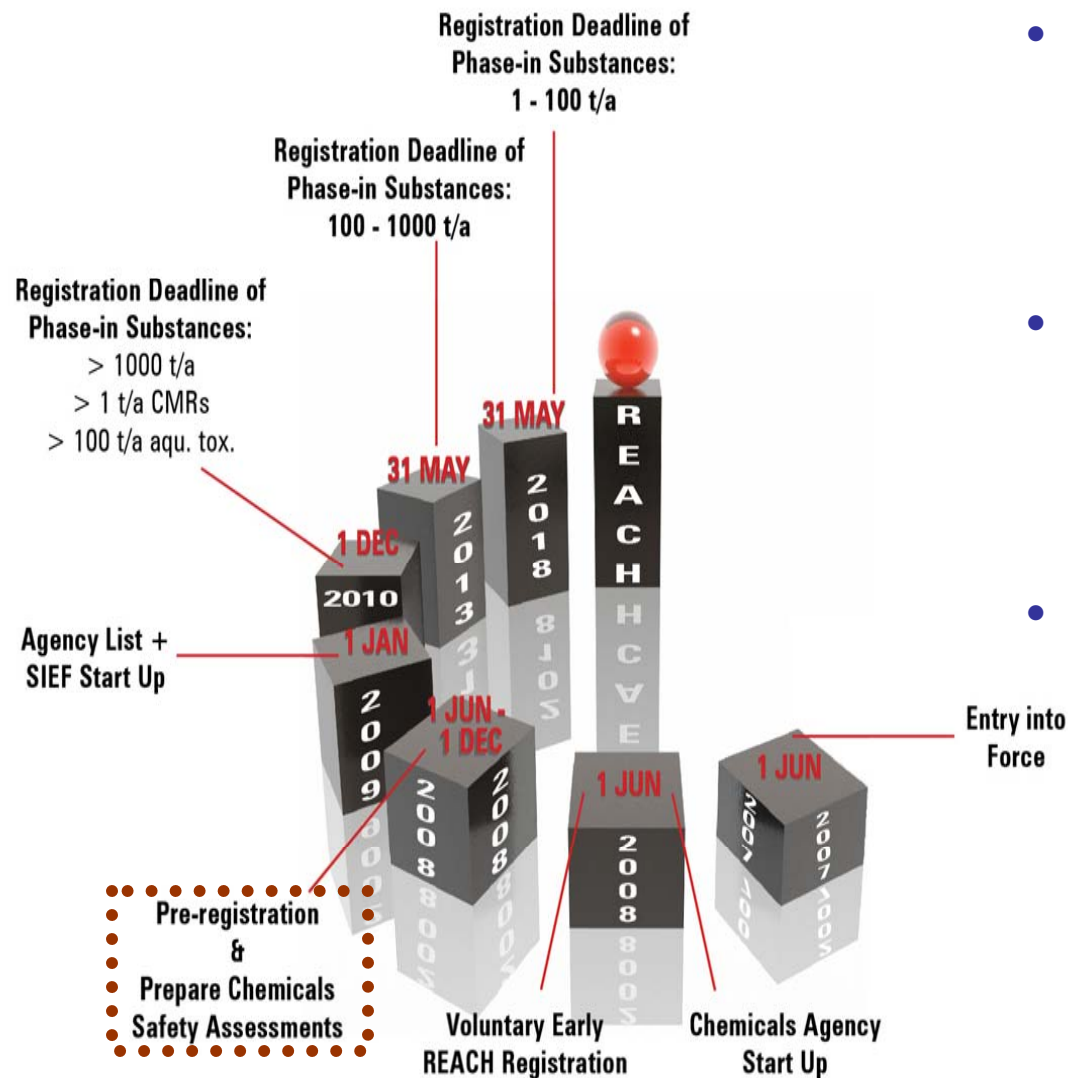
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TOPICS COVERED

- 1. Why Pre-Registration Is Essential (A Reminder)**
- 2. US / EU Perspectives**
 - **Differences**
 - **Similarities**
- 3. Pre-Registration Strategy**
 - **Manage Supply Chain**
 - **Articles**
 - **Polymers**
- 4. Final Thoughts**

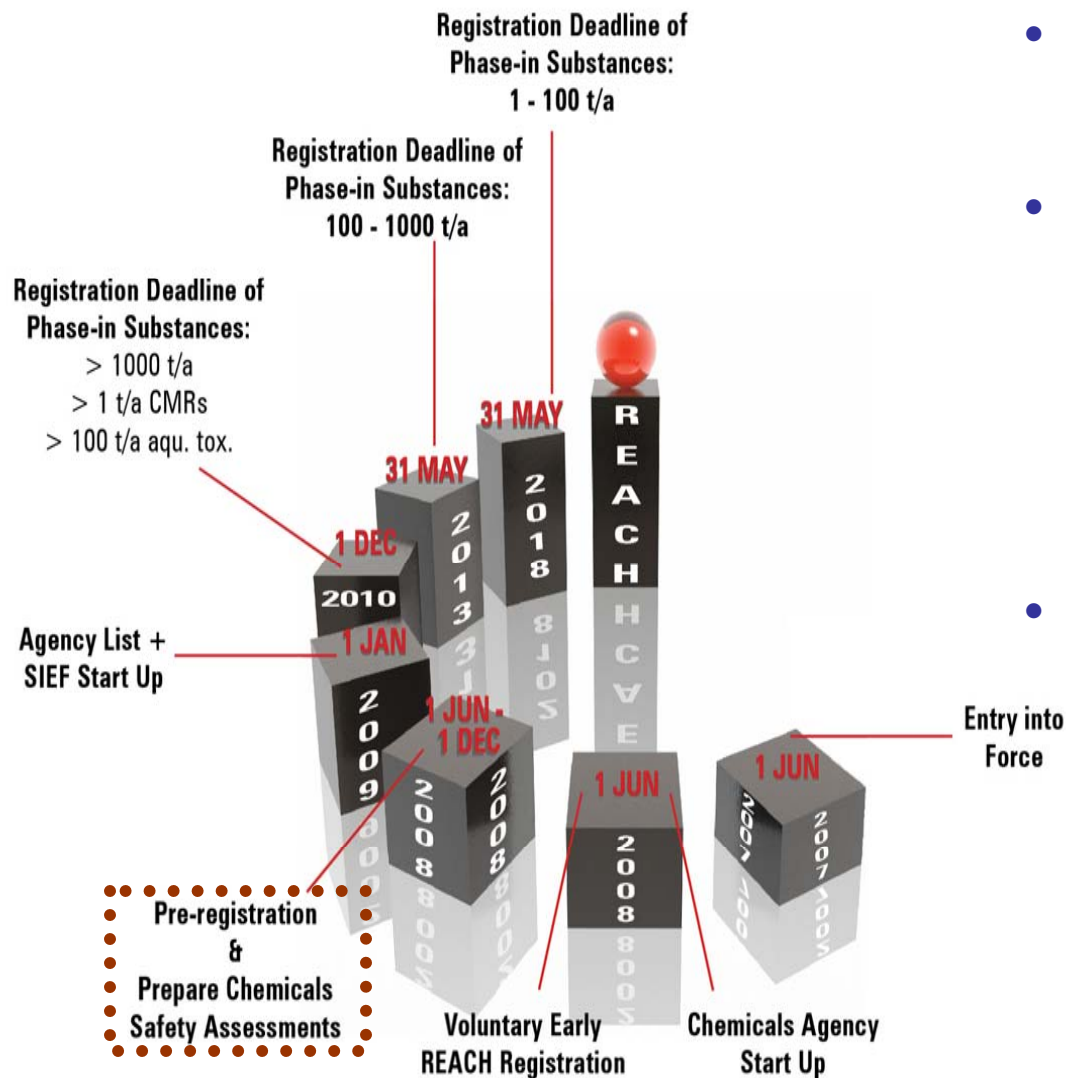
Why Pre-Registration Is Essential

WHY PRE-REGISTRATION IS ESSENTIAL



- **Extends Registration deadlines** for market access of *phase-in* (existing) substances.
- **Sanctions** for any consignment which cleared customs from 1 June 2008 (retrospective liability) if no Pre-Registration.
- **Can you rely on your importer or supplier?**

WHY PRE-REGISTRATION IS ESSENTIAL



- **Pre-Registration does not compel Registration.**
- **Even if you Register immediately (skip Pre-Registration) there will *always* be a market access gap because you must file “inquiry” and suspend activities until complete dossier submitted.**
- **No Fees - at worst you will play a *passive* role in a SIEF.**

US / EU Perspectives

US / EU PERSPECTIVES: DIFFERENCES

US

“I am here with my colleagues from... Korea...to convey our serious concerns with REACH’s workability, its potentially disruptive effects on international trade, and our shared perception that third country concerns have not been factored into the legislative process.”

*U.S. Ambassador to the EU
C. Boyden Gray, 8 June 2006*

EU

“REACH is currently the **most ambitious chemicals legislation in the world**... More information will be available about substances... most dangerous substances will be progressively substituted... This will help improve citizens' health and avoid environmental damages. **REACH will also encourage innovation in the chemicals industry and increase consumer confidence in their products.**”

*EU Environment Commissioner
Stavros Dimas, 18 December 2006*

US / EU PERSPECTIVES: DIFFERENCES

US (and other non-EU) manufacturers and formulators cannot (pre-)register, but must use:

- EU Importer(s)
- an OR (such as Steptoe & Johnson)
- or establish an EU legal entity (as Importer or OR)

EU Importer raises multiple issues:

- confidentiality of CBI
- commercial relationship needs to be very strong for foreseeable future
- importer may lack necessary technical/legal capacity
- role in SIEF data-sharing/compensation activities
- if there are multiple EU importers you have to vet each

Even if you have an EU presence:

- is it the true importer?
- could it be an OR (does it qualify)?

US / EU PERSPECTIVES: COMMONALITY?

US

ExxonMobil

“ExxonMobil will register approximately 1,000 substances... Our goal is to achieve cost effective and seamless implementation.”

Dow

“Dow’s intention to pre-register all of the substances that it... manufactures outside the EU and imports into the EU...”

EU

Euratex

“REACH is one of the most serious challenges facing textile and apparel manufacturing... It ranks in potential impact with the end of the quota system... It requires best possible advice, proper preparation and clear implementation planning.”

US / EU PERSPECTIVES: COMMONALITY?

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

- Enhancing product/brand reputation
- Customer outreach & loyalty
- Industry leadership (reputational, political and marketing benefits)
- Proactive Business Planning (products, competition, sectoral restructuring)
- REACH Compliance = “safety certificate” (long-term confidence)
- REACH requires contact throughout the supply/regulatory chain which can be used to your benefit.

Pre-Registration Strategy

MANAGING YOUR SUPPLY CHAIN

Our work with Non-EU:

- substance manufacturers
- substance formulators
- articles (finished products) manufacturers

underlines that they (and you) must deal with a **complexity of supply chain** management issues (which EU entities do not face to the same extent).

Whatever your business, whatever its size, and whatever your role, proactive management of your supply chain is crucial.

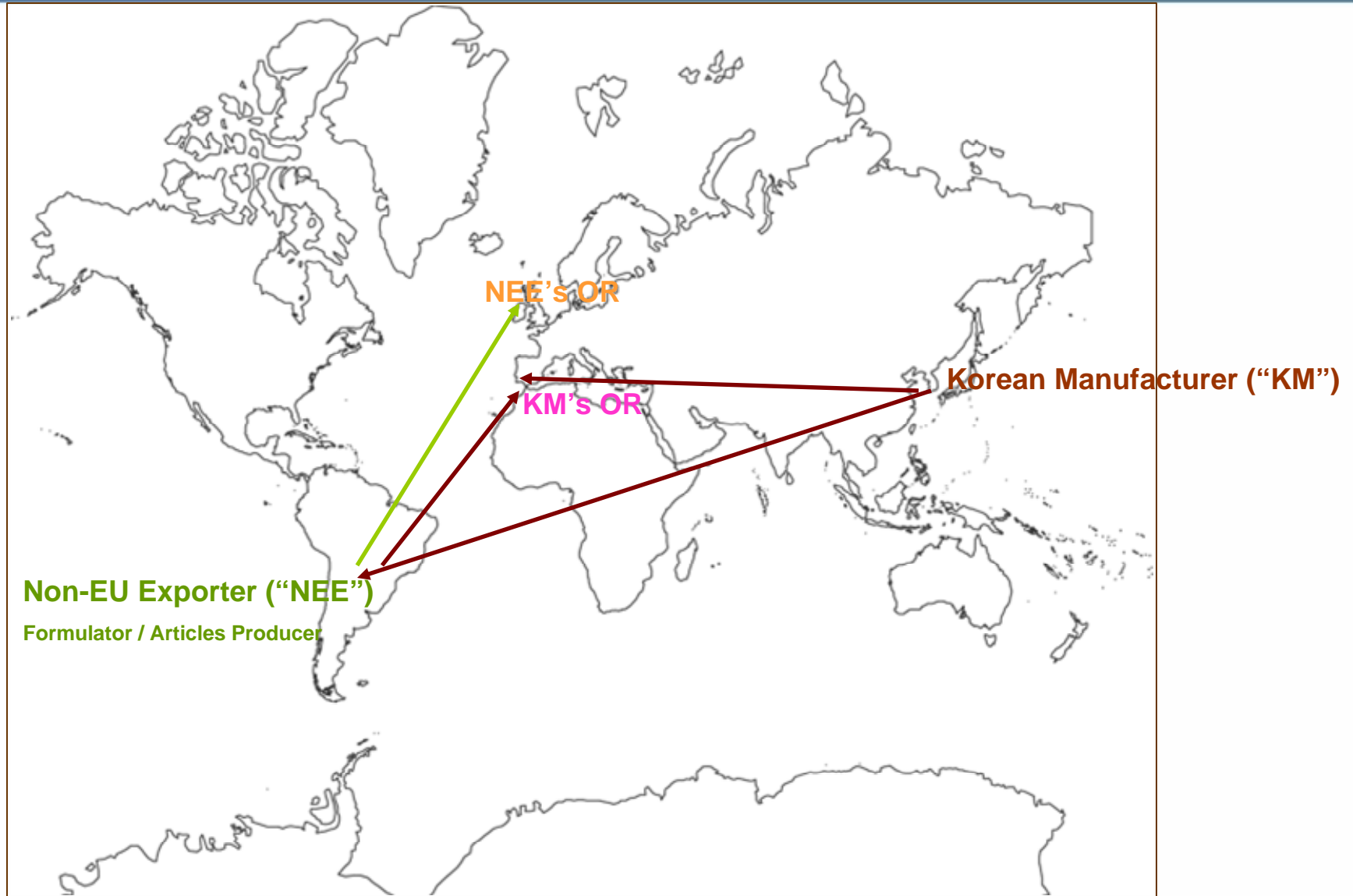
The practical effects of REACH on non-EU supply chain were not properly considered and are now being “fixed” through (non-legally binding) Guidance.

MANAGING YOUR SUPPLY CHAIN

OR no longer required to aggregate export tonnages of all non-EU suppliers it represents for relevant substance:

- avoids being disadvantaged by heavier and earlier Registration requirements than EU based M/Is of equivalent tonnages)
- eligibility for SME Registration fee reduction based on size of each (not aggregated) supplier represented by OR (Article 12, Regulation (EC) 340/2008)

MANAGING YOUR SUPPLY CHAIN



MANAGING YOUR SUPPLY CHAIN

Non-EU manufacturer can ask Non-EU downstream actor to agree to let it register its tonnage rather than actor appoint its own OR: avoid passing CBI to downstream non-EU actor.

Can it decide that a certain volume of relevant substance will not be included in OR's Registration but left to EU based importer to register (i.e. "splitting")?

Formulators or articles producers can appoint OR instead of the Non-EU manufacturer so doing.*

Does it need agreement of **all** non-EU downstream actors not to appoint their own OR for that tonnage?

* 4th meeting of REACH CAs June 16-17.

MANAGING YOUR SUPPLY CHAIN

Changing your OR if dissatisfied: ‘...the successor [OR] can submit an update of the earlier Registration dossier provided that the earlier only representative agrees to the change’ (latest May 2008 ECHA Registration Guidance):

- need to prove agreement with previous OR in update
- appropriate provisions in OR agreement dealing with change of OR

ARTICLES (FINISHED PRODUCTS)

REACH places specific duties and obligations on manufacturers, importers and downstream users of substances in articles*. The supply chain for finished products – and not only chemical companies – has to deal with REACH.

Most commonly used objects in private households and industries are articles:

- electronic equipment
- furniture
- clothes
- vehicles
- books
- toys
- kitchen equipment

Parts/components may in themselves be articles. Also packaging.

Think about what is being manufactured or imported.

*

- 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

Art. 3(3)

ARTICLES

Think about how your production process could expose you to or protect you from additional REACH requirements.

Registration

‘intended to be released under *normal or reasonably foreseeable* conditions of use’. **Art. 7(1)**

Avoid importing substances/preparations into EU for assembly.

Notification

SVHCs with ‘exposure to humans or the environment during normal or reasonably foreseeable conditions of use *including* disposal’. **Art. 7(2)**

Can you *exclude* exposure? Is it more expensive than notification – calculate!

What about substitution?

What about components?

**PRESENT ABOVE A CONCENTRATION OF
0.1 % WEIGHT BY WEIGHT**

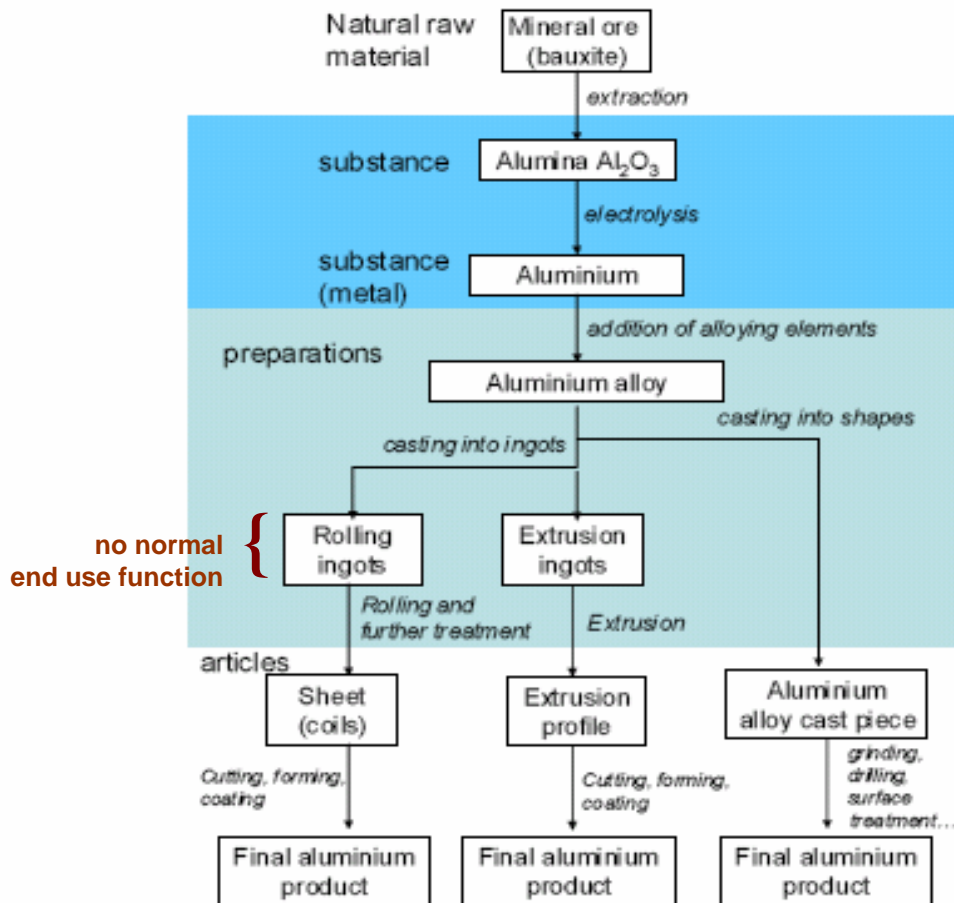


Austria, Belgium, Denmark, France, Germany & Sweden

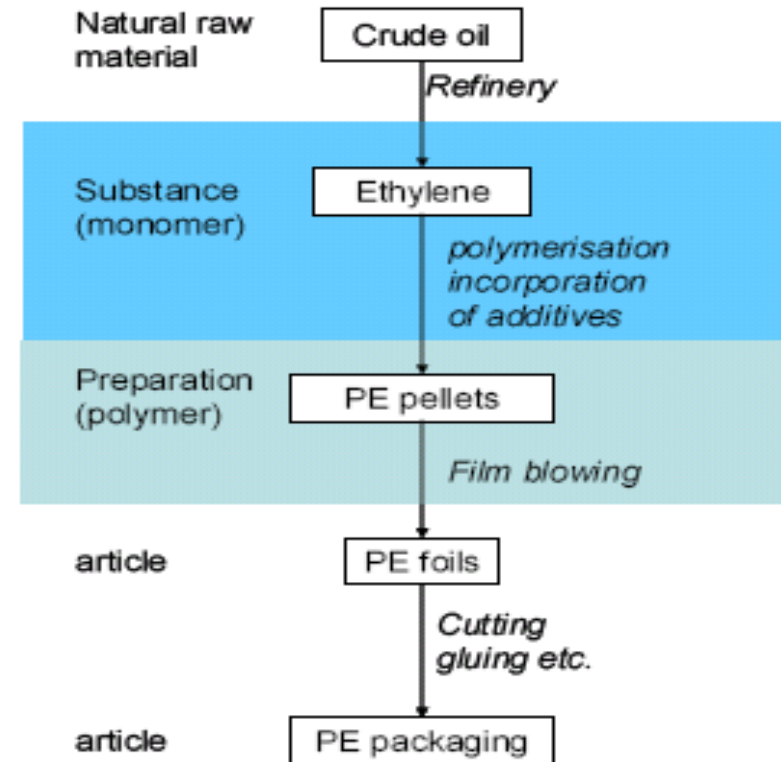
ARTICLES: BORDERLINE CASES

Processing may – at a certain point – turn a natural or synthetic material from being a substance/preparation into an article (e.g. polymer pellet converted to film, bauxite into an aluminium sheet or crude oil into PE packaging).

Aluminium products



Plastic products



Articles Guidance p.82 & 88

ARTICLES: DEFENSIVE PRE-REGISTRATION

- Registration & Notification are not compulsory for substances which have already been registered for the *specific* use in an article i.e. someone must do Reg./Notif. but not necessarily you. [Art. 7(6)]
- However, at the time of Pre-Registration very few substances will have been registered. This means that the only way to secure uninterrupted market access is to ensure Pre-Registration now (a decision on Registration can be taken later).
- Pre-registering will only be certain if you have legally binding (respected) commitments from those in your supply chain (hard to achieve), so pre-registering yourself should be seriously considered.

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.

ECJ reference 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

POLYMERS

Additives in Polymers:

- A polymer can contain additives necessary to preserve the stability of the polymer and impurities deriving from the manufacturing process. These stabilisers and impurities are considered to be part of the substance and do not have to be registered separately. Stabilisers include:
 - heat stabilisers,
 - anti-oxidants (both useful during extrusion) and
 - light stabilisers (e.g. for preservation during use).
- Impurities are unintended constituents of the polymer such as catalysts residues or unreacted monomers.

POLYMERS

Substances in polymers:

- Substances may be added to improve the performance of the polymer even though they are not necessary for preserving the stability of the polymer.
- Examples of such substances include:
 - pigments
 - lubricants
 - thickeners
 - antistatic agents
 - antifogging agents
- When a polymeric material contains such substances it should be considered as a preparation or an article, and for such substances normal (Pre-)(Pre-)Registration requirements apply.

FINAL THOUGHTS

- Integrated (technical /legal) compliance “strategy” is essential
- Top management must be involved in critical decision-making
- Ensure adequate infrastructure in place to deal with REACH (support and data-handling systems)
- Complete inventory (examining exemptions)
- “No Data No Market” – threatens EU market presence/reputation. Competitors/customers will be watching
- Early Pre-Registration will facilitate consortia membership
- Find out what will be supported upstream (get binding undertakings)
- **REACH compliance cannot be left to chance**



THANK YOU

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Step toe REACH Services

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www.step toe.com/REACH



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What is REACH?
The Regulation (EC) 1907/2006 on Registration, Evaluation and Authorisation of Chemicals (REACH) establishes a new EU chemicals regime. The central policy objective is to transfer responsibility for the generation of data on the safety of chemical substances from governmental authorities to industry. It is expected to affect some 30,000 existing chemical substances, most of which will need to be Pre-Registered by 1 December 2008. Time limits apply and must be respected in order to maintain market access. Substances of Very High Concern may need to be Authorised. Other Restrictions may also apply. REACH also forces a new approach to the sharing of data and to supply chain relationships.