



# REACH in Practice: Lessons Learned

*Presenters:*

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# Only Representative: Recent Changes in Interpretative Guidance and Remaining Questions

*REACH Pre-registration Webcast*

*July 9, 2008*

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## Only Representative: Background to Changes in Interpretative Guidance

- Non-EU based suppliers cannot register directly
- Appoint OR to avoid disclosure of CBI
- Practical effect of REACH on non-EU supply chain not properly considered
- OR requirement a discriminatory trade barrier for non-EU suppliers (vis-à-vis EU based competitors)?
- Pressure from non-EU based industry on Commission and ECHA to (re)-interpret Regulation fairly

## Only Representative: Appointment by More Than One Supplier of Same Substance

- Requirement for separate registration for each non-EU supplier of same substance
- OR not required to aggregate export tonnages of all non-EU suppliers it represents for relevant substance
  - ✓ avoids non-EU suppliers 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)
  - ✓ avoids non-EU suppliers missing fee reductions enjoyed by EU based competitors of equivalent size

## Only Representative: Appointment by Non-EU Manufacturer Not Directly Exporting to EU

- Can a non-EU manufacturer appoint an OR for tonnages of a substance exported into EU territory 'indirectly' (by those in manufacturer's non-EU downstream supply chain)?
- May 2008 ECHA Registration Guidance: Indirect exporter can appoint OR if export undertaken by non-EU based distributor, but what about other non-EU downstream actors?
- 4th meeting of REACH CAs June 16-17 2008 confirms Commission interpretation that indirect exporter can appoint OR where export undertaken by downstream non-EU based formulators or articles producers:

## Only Representative: Appointment by Non-EU Manufacturer Not Directly Exporting to EU

‘REACH does not distinguish between direct and indirect imports into the EU...As long as it is clear for which imports the OR is responsible, it does not matter what are the steps or supply chain outside the EU between the manufacturer, formulator or producer of an article and the importer in the EU’ (suggested amendment to ECHA Registration Guidance).

- Non-EU manufacturer can ask downstream actor to agree to let it register its tonnage rather than actor appoint its own OR:
  - ✓ strategically preferable: avoid passing CBI to downstream non-EU actor?
  - ✓ Results in equal treatment of non-EU and EU manufacturers

## Only Representative: Change of OR

- Latest May 2008 ECHA Registration Guidance:

‘If a “non-Community manufacturer” decides to change his only representative, the successor will have to submit a new registration dossier, as there is no link between the two only representatives who are separate legal entities’ (section 1.5.3.4, page 23).

- Unfair restriction and burden on non-EU suppliers, particularly compared with EU manufacturers

## Only Representative: Change of OR

- Amendment to ECHA Registration Guidance suggested at CAs meeting:

‘If a “non-Community manufacturer” decides to change his only representative, the successor can submit an update of the earlier registration dossier provided that the earlier only representative agrees to the change’ (return to position in June 2007 Registration Guidance).

- Need to prove agreement with previous OR in update
- Appropriate provisions in OR agreement dealing with change of only representative

## Only Representative: Points Still to be Clarified

- ECHA states at CA meeting that following question needs clarification:
  - ✓ ‘Is the whole volume of a substance manufactured by a “non-Community manufacturer” and exported to the EU (directly or from any point in the Community supply chain) to be covered by the registration of the only representative he has appointed?’
- Meaning of question unclear
- MEANING 1: That appointment of OR by indirect exporter may preclude appointment of OR for same substance by downstream non-EU actors in same supply chain

## Only Representative: Points Still to be Clarified

- ✓ ability of indirect exporter to appoint an OR would depend on obtaining agreement of **all** non-EU downstream actors not to appoint their own OR
- ✓ realistic for indirect exporter to know which, among its non-EU purchasers, export finally to EU and in what amounts?
- MEANING 2: That a non-EU supplier (whether direct or indirect exporter) which appoints an OR could decide that a certain volume of relevant substance will not be included in OR's registration but left to EU based importer to register
  - ✓ generally assumed to date that OR would register **all** appointor's exports of substance (except tonnages registered by another OR appointed by non-EU based downstream actor)

## Only Representative: Points Still to be Clarified - Late Pre-Registration

- ECHA states at CA meeting following question:
  - ✓ ‘What are the conditions under which an only representative can benefit from Article 28.6 of the REACH Regulation (late pre-registration), if any?’
- Wording of late registration provision aimed at EU based entities only?
- But OR shall comply with ‘all other obligations of importers under this Regulation’ (Article 8(2))

## Only Representative: Concluding Comments

- OR clarification welcome but lack of legal certainty, both to date and on remaining issues, problematic for REACH compliance:
  - ✓ Separate registration requirement = cost implications for ORs who already agreed to represent several non-EU suppliers of same substance
  - ✓ OR appointment by indirect exporter clarification too late? Non-EU downstream actors already appointed ORs prior to pre-registration
  - ✓ OR agreements already executed:
    - without provisions permitting update by new OR
    - too late to decide to now exclude tonnage of certain EU importer

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# Articles under REACH

*REACH Pre-registration Webcast*

*July 9, 2008*

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# KEY POINTS

- 1. What is an article?**
- 2. When to (pre-)register?**
- 3. When to notify?**
- 4. Information requirements**
- 5. Important practical measures**

# REGISTRATION & NOTIFICATION OVERVIEW

**REACH places specific duties and obligations on:**

- **manufacturers**
- **importers**
- **downstream users**

**of substances contained in articles (finished products). The supply chain for finished products - and not only chemical companies – has to deal with REACH.**

**Substances in articles may be subject to:**

- **registration** ~ if intentional release
- **notification** ~ for SVHCs exposed (un/intentionally) to humans or environment
- **neither** ~ no intentional release or SVHC exposure

**If registration or notification applies to your products you need to understand:**

- **who *must* do it**
- **who *may* do it (and commercial reasons for so doing)**

# WHAT IS AN ARTICLE?

## **An article is:**

- 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)

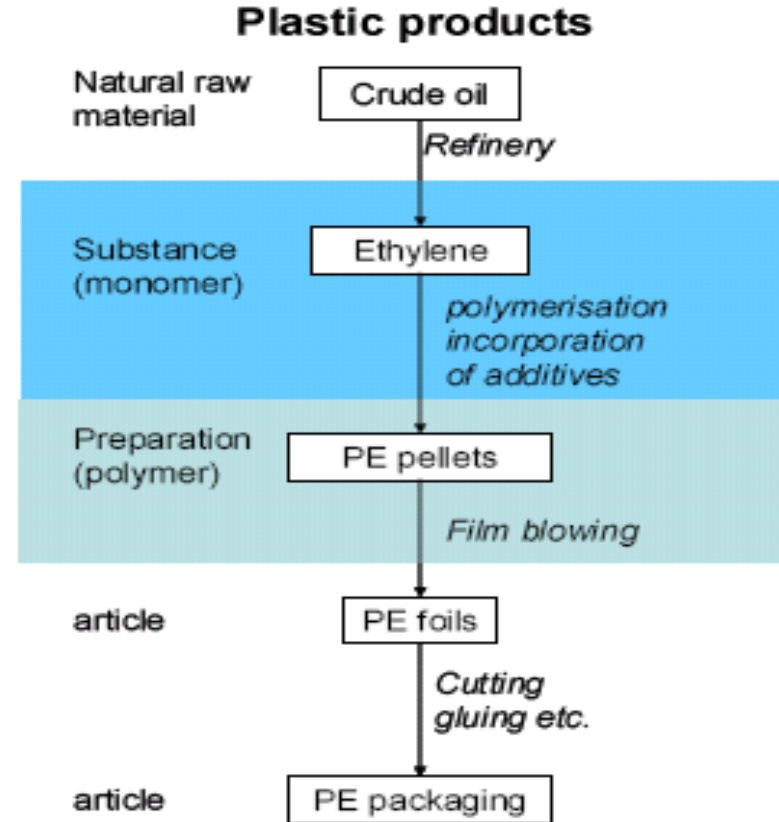
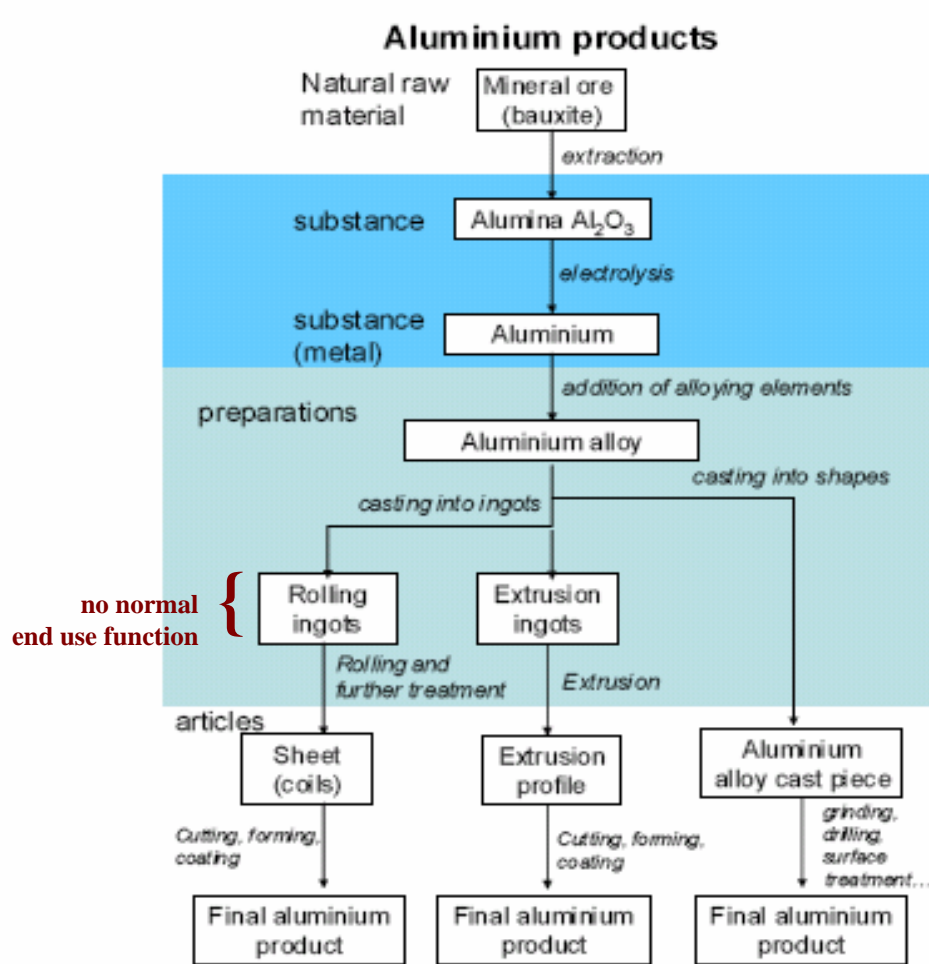
## **Most commonly used objects in private households and industries are articles:**

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

**Parts in themselves may be articles. Think about what is being manufactured or imported.**

# 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).



# ARTICLES: BORDERLINE CASES

The distinction between:

- Containers/special carrier materials (normally solid), *in/on which there are* substances/preparations [Article/Substance split]

Examples: toner cartridge, wipe (with cleaning fluid), and spray can (with paint)

This means that the substance/preparation *is subject to* all applicable REACH requirements.

- Articles *with integral* substances/preparations (solid, liquid or gaseous) [Pure Article]

Examples: thermometer, battery, and car tyres

This means that only rules on notification of substances *might* apply.

# REGISTRATION

Any producer\* or importer<sup>+</sup> of articles shall submit a **registration** (general **deadlines for pre-registration** and registration apply) to the Agency for **any substance** contained in those articles, if it is:

- (a) present in those articles in quantities totalling **> 1 tonne**<sup>o</sup> per producer or importer per year; and
- (b) **intended to be released** under *normal or reasonably foreseeable* conditions of use.

Art. 7(1)

\* Makes or assembles an article within the Community

<sup>+</sup> Established within the Community and responsible for import

<sup>o</sup> The amount registered is the total volume in the article – not just what is intended to be released

# REGISTRATION

*“intended to be released*

*under normal or reasonably foreseeable conditions of use”*

- **2 conditions**, so foreseeable but unintentional release not covered
- article must have an **accessory** (rarely primary) **function** achieved through the release i.e. provides **“added value”** not directly connected to end use function (a scented eraser)
- intention determined with regard to the **producer’s intentions**

Unintended release includes during:

- **removal of impurities** from semi-finished/finished article during production (sizing)
- **maintenance** designed to improve quality but not function e.g. consumer washing clothes (removing dye/starch etc.)
- **unavoidable side-effect** of functioning or article (break linings)
- **formed during chemical reactions** (ozone from copy machines)

# REGISTRATION

“*intended to be released*  
under *normal or reasonably foreseeable conditions of use*”

## Normal

- use related to intended function (see user manual/instructions)
- different standard for consumers and professional users
- you can control normal use (do not wash above 30<sup>o</sup> C)

## Reasonably Foreseeable

- not as intended but which can be anticipated because of article’s form, shape or function (e.g. breakage of fragile containers or intensive use)
- excluded – uses advised against, or excluded by producer or clear misuse

# REGISTRATION: ECHA POWER

ECHA has **residual power to require registration** of any *unintentionally* released substance if:

- (a) present in article > **1 tonne** per producer or importer per year; and
- (b) ECHA has grounds for suspecting that:
  - (i) the substance **is released** from the articles, and
  - (ii) the release of the substance from the articles presents a **risk to human health or the environment**.

Art. 7(5)

# NOTIFICATION

Any producer or importer of articles shall **notify** the Agency **if a substance** is present in those articles which:

- **meets the criteria in Article 57** (i.e. a SVHC which may be listed in Annex XIV and be subject to Authorisation);
- is **identified** in accordance with Article 59(1) (i.e. identification of Art. 57 **candidate list** substances); present in those articles >1 tonne per producer or importer per year; **and**
- present **above a concentration of 0.1 % weight by weight.**

Art. 7(2)

**AND** there is **exposure** to humans or the environment during normal or reasonably foreseeable conditions of use ***including disposal.***

Notification requirement **applies 6 months after** a substance is **identified**, from 1 June 2011.

# 0.1 % WEIGHT BY WEIGHT



**Austria, Belgium, Denmark, France, Germany & Sweden**



# NOTIFICATION

Notification information *must include*:

- identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;
- registration number(s) referred to in Article 20(1), if available;
- identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;
- classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;
- brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);
- tonnage range of the substance(s)

# NOTIFICATION

Notification not required if:

- producer or importer **can exclude exposure** to humans or the environment
- during *normal* or *reasonably foreseeable* conditions of use
- **including disposal** (implications for end of life treatment)

In such cases, the producer or importer shall supply “appropriate instructions” to the recipient of the article.

**Excluding exposure may be more expensive than notification – calculate!**

Art. 7(3)

# INFORMATION REQUIREMENTS

**Duty on “any supplier of an article”** to communicate to the recipient (excluding consumer), **“sufficient information”** on substances in it if meets criteria for notification. (Information requirement is linked to the existence of a candidate list.)

**Supplier of an article:** any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market\*.

**Sufficient information:** that which is available to the supplier, to allow *safe use* of the article including, as a minimum, the name of that substance. No mandatory format but Guidance makes suggestions.

**Freestanding obligation - no requirement that recipient asks for information.**

Silent on fees - implies that these may be permitted.

Article 33(1)

\* Placing on the market means: supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.

# INFORMATION REQUIREMENTS

If *consumer requests* information then same requirement to supply “*sufficient information*” applies (for substances which meet the same criteria):

- free of charge
- within 45 days of receipt of the request

Expect requests from consumer NGOs.

Article 33(2)

# IMPORTANT PRACTICAL MEASURES

- 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.**
- Supply chain relationships will need to deliver substantial amounts of information which articles producers/importers are not used to having.
- Systems need to be in place in order to:
  - ✓ collect this information rapidly, and
  - ✓ facilitate provision of information on demand

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# REACH: Guidance Updates and Non-Compliance

*REACH Pre-registration Webcast*

*July 9, 2008*

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# Topics

1. Updated guidance discussed during this presentation:
  - PPORD
  - Monomers and Polymers
  - Intermediates
  - Registration
2. Non-compliance: inspections by the Dutch Authorities
3. REACH news

## Guidance: **WARNING**

None of the guidance is legally binding. The guidance is being used to supplement (and sometimes, in effect, to try to correct errors in) the REACH Regulation. Therefore:

- Always check what the REACH Regulation actually says before reviewing the guidance.
- In situations where the guidance and the Regulation conflict there is a risk that EU Member States or competitors could challenge ECHA's decisions taken on the basis of guidance which does not properly follow the Regulation.

## Guidance for Industry

### ➤ Guidance available for:

- ✓ Registration;
- ✓ Data sharing;
- ✓ Downstream user;
- ✓ Intermediates;
- ✓ Monomers and Polymers;
- ✓ Scientific R&D and product and process oriented R&D; and
- ✓ Substances in articles.

### ➤ Guidance not available for:

- ✓ Pre-registration;
- ✓ Socio-economic analysis for authorisation;
- ✓ Classification and labelling notification; and
- ✓ Preparation of an application for authorisation.

## Guidance: PPORD

- Product and process oriented research and development (PPORD) in quantities of 1 tonne per year or more:
  - ✓ The substance is exempted from registration but it is important to check whether the substance is:
    - handled in reasonably controlled conditions in accordance with legislation for the protection of workers and the environment, and
    - is only made available to selected customers.
  - ✓ If a substance is also manufactured/imported for a purpose other than PPORD in quantities of one tonne or more per year, then it has to be registered like any other substance but the quantity covered by the PPORD notification does not need to be taken into consideration for registration purposes.

# Guidance: PPORD

- Substance variation:
  - ✓ The notifier has to ensure that possible variations in the composition of the substance (that may be foreseen under the scientific experimentation) are taken into consideration.
  - ✓ If the substance composition varies, it should be carefully evaluated whether this could have some impact on the classification and labelling of the substance.
- Updates must be submitted if any of the following change:
  - ✓ the identity of a PPORD notifier;
  - ✓ the tonnage band specified in the PPORD notification;
  - ✓ the identity of the substance;
  - ✓ the classification and labelling;
  - ✓ the list of customers considered relevant; or
  - ✓ if the substance composition varies and this is not already described in the notification.

## Guidance: PPORD

### ➤ **Clarification on Confidentiality:**

- ✓ ECHA and the competent authorities of the Member States concerned must always keep confidential any information submitted by the manufacturer, importer or downstream user of a substance for the purpose of PPORD. This information will not be published on the Internet.

# Guidance: Monomers and 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.

## Guidance: Monomers and 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; and
    - antifogging agents.
  - ✓ When a polymeric material contains such substances it should be considered as a preparation or an article, and for such substances normal registration requirements apply.

## Guidance: Intermediates

1. If an on-site isolated intermediate or transported intermediate is only manufactured or used under strictly controlled conditions it may go through an abbreviated registration process (Articles 17 and 18).
  2. If the manufacturer or importer (M/I) of a substance manufactures or imports the substance for other purposes than only the use as an intermediate, or if the manufacture or use(s) are not under strictly controlled conditions, then the M/I needs to submit a “standard” registration dossier.
- What if part of the tonnage is manufactured and used under (1) and part of the tonnage is manufactured and used under (2)?

## Guidance: Intermediates

- The registrant will submit one registration dossier covering his total tonnage.
  - ✓ The information requirements will be based on the tonnage for non-intermediate uses and for intermediates not used under strictly controlled conditions (number 2 above).
  - ✓ The part of the tonnage M/I as an intermediate under strictly controlled conditions will not be taken into account for the information requirements (number 1 above).
  - ✓ However, the use as an intermediate should be documented in the dossier, including the volume manufactured or imported for this purpose.
  - ✓ Fees: they will be calculated independently for the use as intermediate under strictly controlled conditions (fees for intermediates) and for the other uses (standard fees).

# Guidance: Registration

- Importation into the EU: shipping companies
  - ✓ It is a case-by-case analysis.
  - ✓ The responsibility for import depends on many factors such as:
    - who orders;
    - who pays; and
    - who is dealing with the customs formalities.
  - ✓ The shipping company that is transporting the substance or preparation normally has no obligations under REACH.  
**Exceptions may occur.**
- “Sales agency:” if the entity is only a facilitator, it transmits an order from a buyer to a non-EU supplier (and is paid for that service), it takes no responsibility whatsoever for the goods or the payment for the goods and at no time takes ownership of the goods, **it is not the importer.**

## Guidance: Registration

- The general provisions on access to information are as follow:
  - ✓ Information in Article 119 (1) and submitted in the registration dossier will be made publicly available on the Agency website.
  - ✓ A registrant may identify certain information in his registration as commercially sensitive (see Article 10(a)(xi)). If the justification with regard to information listed in Article 119(2) is accepted by ECHA, this information must not be published on the Agency website.
  - ✓ Access to such pieces of information and other pieces of information may be granted by the Agency on request on a case-by-case basis. If it is not clear whether a document may be disclosed, the Agency will consult the owner of the document with a view to assessing whether it should be disclosed.

# Guidance: Registration

## **Published/Disclosed:**

- *the name in the IUPAC Nomenclature, for dangerous substances;*
- *the name of the substance as given in EINECS (if applicable);*
- *the classification and labelling of the substance;*
- *physicochemical data concerning the substance and on pathways and environmental fate;*
- *the result of each toxicological and ecotoxicological study;*
- *any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC)*
- *the guidance on safe use; and*
- *analytical methods if requested (Annexes IX or X) to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.*

## **Normally NOT Published/Disclosed:**

- *details of the full composition of a preparation;*
- *the precise use, function or application of a substance or preparation, including information about its precise use as an intermediate;*
- *the precise tonnage of the substance or preparation manufactured or placed on the market; and*
- *links between a manufacturer or importer and his distributors or downstream users.*

# Non-Compliance

## ➤ The Dutch Authorities:

- ✓ The Health and Safety Inspectorate is targeting professional and industrial users;
- ✓ The Food and Consumer Product Safety Authority is targeting manufacturers, importers and traders of preparations and articles for consumers; and
- ✓ The Inspectorate of the Ministry of Housing, Spatial Planning and the Environment targeting manufacturers, importers and traders of substances, preparations and articles for professional use.

# Non-Compliance

- Professional users are being inspected throughout the year, particularly concerning:
  - ✓ Delivery and use of Safety Data Sheets (SDSs) and
  - ✓ Collecting information from chemical product suppliers.
- Manufacturers and Importers are being inspected beginning July 2008, particularly concerning:
  - ✓ Correct labelling;
  - ✓ Collecting information from customers; and
  - ✓ Control of non-phase in substances
- Traders are being inspected beginning July 2008, particularly concerning:
  - ✓ Correct labelling;
  - ✓ Collecting information from customers
  - ✓ Passing on information in the supply chain (including SDSs).

## REACH News

- The first public consultation has opened on 16 proposals for the identification of Substances of Very High Concern (SVHC). These proposals have been prepared by Member States with the view to include these chemicals into the first “candidate list” of substances that eventually may be subject to authorisation. The consultation will close on 14 August 2008.
- Data Submission Manual 5: How to Complete a Technical Dossier for Registration and PPORD Notification.
- Check the ECHA website regularly!



# REACH

## “Substance” identification

*REACH Pre-registration Webcast*

*July 9, 2008*

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# Agenda

1. Why is identification of chemical substances necessary for REACH?
2. What is a chemical substance under REACH?
3. How is a chemical substance identified?
4. Next Steps after identification?

# Why is identification of chemical substances necessary for REACH?

## ➤ Article 1- Aim and Scope

REACH concerns the manufacture, import, placing on the market and use of substances on their own, in preparations or in certain articles.

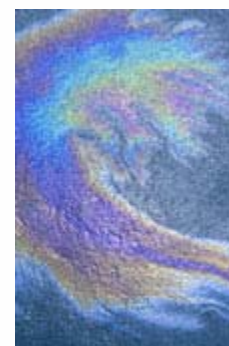
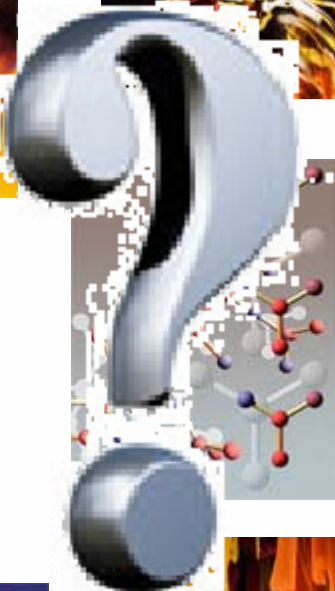
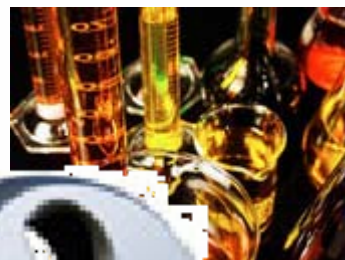
(Preparations and articles as such are not regulated in REACH)

**REACH is substance based**

## Why is identification of chemical substances necessary for REACH?

- To **ensure** a properly working **REACH** system, substance **identification** is **essential**;
- Substance identification **requires expertise** and clear, practical **rules**;
- There are **different views** on how substance identification could (or should) be approached... parties need to agree on a **common approach**.

# Chemical Substance, Preparation, Articles?



# What is a chemical substance under REACH?

## Article 3(1) - Substance

*“a chemical element and its compounds in the natural state or obtained by any manufacturing process,*

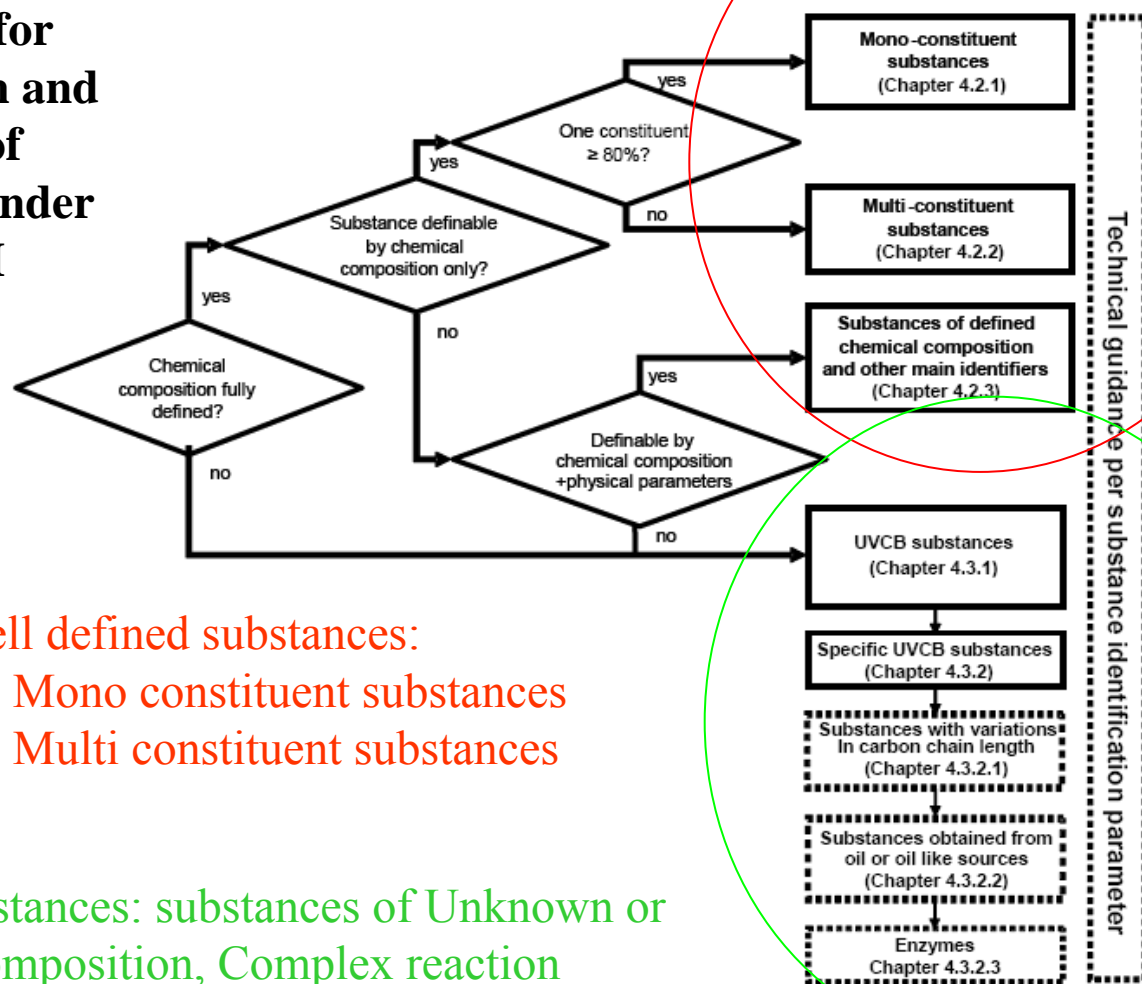
*including any additive necessary to preserve its stability and any*

*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.”*

# How is a chemical substance identified?

## **Figure 4.1 -** **Guidance for** **identification and** **naming of** **substances under** **REACH**



Well defined substances:

- Mono constituent substances
- Multi constituent substances

UVCB substances: substances of Unknown or Variable composition, Complex reaction products or Biological materials

## *Well defined: mono constituent substances*

1. Chemical composition: one main constituent  $> 80 \%$ ;
2. Chemical identity: based on the main constituent (name, CAS-number, EC-number, etc.)
3. Typical concentration and range must be provided
4. Impurities relevant for classification or present in a concentration  $\geq 1 \%$  to be specified

### **Example:**

<b>Main Constituent</b>	<b>%</b>	<b>Impurity</b>	<b>(%)</b>	<b>Name</b>
m-xylene	91%	o-xylene	5	<b>m-xylene</b>
o-xylene	87%	m-xylene	10	<b>o-xylene</b>

## *Well defined: mono constituent substances*

Deviation from >80% is possible with **justification**, for instance if:

- the range of concentrations for the main constituent and the impurities overlap at 80% and the main constituent is only occasionally  $\leq 80\%$ .
- the main constituent is  $<80\%$  but the substance can be shown to have similar physico-chemical properties and the same hazard profile as other mono-constituent substances with the same identity that fulfil the 80% rule.

## *Well defined: multi constituent substances*

1. Chemical composition: mixture of main constituents each between 10 - 80 %;
2. Chemical identity: by each main constituent (“mixture of ..”)  
*The difference between preparation and multi-constituent substance is that a preparation is gained by blending of two or more substances without chemical reactions whereas a multi-constituent substance is the result of a chemical reaction i.e. result of a manufacturing process*
3. Typical concentrations and ranges must be provided
4. Toxicological significant and relevant Impurities must be specified (impurities present in a concentration  $\geq 1$  % and relevant for classification)

### **Example:**

<b>Main constituents</b>	<b>Content</b>	<b>Impurity</b>	<b>Content (%)</b>	<b>Name</b>
m-xylene o-xylene	50 45	p-xylene	5	<b>Mixture of m-xylene and o-xylene</b>

## *Well defined substances & other main identifiers*

*Well defined: Some substances are defined by more than their chemical composition, e.g. some crystalline inorganic minerals*

- ✓ Chemical composition as mono- or multi-constituent substance

**AND**

- ✓ Other physical or characterisation parameters: e.g. crystallomorphology, (geological) mineral composition.

**Example:**

Name	CAS #	EINECS	Additional description
Cristobalite	14464-46-1	238-455-4	O <sub>2</sub> Si ( <b>Crystal structure: cubic symmetry</b> )

# UVCB substances

## RIP 3.10 definition:

*“Substances of **Unknown or Variable composition, Complex reaction products or Biological materials**”*

- Chemical composition: undefined or variable
- Chemical identity based on:
  - ✓ Source (e.g. plant specie)
  - ✓ Process (e.g. extraction)
  - ✓ Other (e.g. enzyme index)
- Chemical identity is depending on the UVCB:
  - ✓ E.g. “...extraction” “reaction product of ...”
- Concentrations and ranges can vary and must be provided
- The terms “main constituents” and “impurities” are normally not relevant for identification of UVCB substances

## Examples of UVCB substances

- Lavender, *Lavandula hybrida*, ext., acetylated
- Fatty acids, coco, reaction products with diethylenetriamine
- *Saccharomyces cerevisiae*, extract
- Reaction product of (2-hydroxy-4-(3-propenoxy)benzophenone and triethoxysilane) with (hydrolysis product of silica and methyltrimethoxysilane)
- Organotungsten compound concentrate (reaction products of tungsten hexachloride with 2-methylpropan-2-ol, nonylphenol and pentane-2,4-dione)
- Soybean meal, protein extn. Residue
- Oxidised logwood (*Haematoxylon campechianum*) extract
- Proteinase, *Bacillus neutral*
- Elastase (pig pancreas)

## Next steps after identification?

### ➤ **Substance identification data required for pre-registration**

#### *Examples of information to be provided at pre-registration:*

- ✓ **Name(s) in the IUPAC nomenclature or other international chemical name(s)**
- ✓ **EINECS/ELINCS number if available and appropriate**
- ✓ **CAS number if available**
- ✓ **CAS name if available**
- ✓ **Substance(s) which you intend to use for read-across approach or (Q)SAR**
- ✓ **Tonnage band**

### ➤ **Joining a substance SIEF**

## Next steps after identification?

### Substance identity & SIEFs:

- The REACH Regulation requires that all Potential Registrants and Data Holders for the "same" phase-in substance shall be participants in a SIEF.
- REACH Regulation neither defines “same substance” nor contains provisions related to establishing the sameness.
- European Chemicals Agency (“ECHA”) does not participate in the discussions between Potential Registrants and there will be no role of ECHA in confirming or rejecting the creation of a particular SIEF.

# Criteria for examining “sameness”

## Examples of criteria used to determine “sameness”:

- The “ $\geq 80\%$ ” rule for mono-constituent substances as well as the “ $< 80\%/ \geq 10\%$ ” rule for multi-constituent substances should be applied
- Hydrates and water free forms (anhydrous) of compounds shall be regarded as the same substance
- Acids or bases and their salts shall be regarded as different substances
- Individual salts (e.g. sodium or potassium) shall be regarded as different substances
- Branched or linear alkyl chains shall be regarded as different substances
- Substances with alkyl groups using additional terms like iso, neo, branched etc, shall not be regarded the same as the substances without that specification
- A multi-constituent substance is not regarded equal to a substance with only a subset of the single constituents
- A substance which is characterised by a species/genus is not regarded as the same as a substance isolated from another species/genus

## Guidance on “same” substance

- REACH Implementation Project - RIP 3.10 Guidance for identification and naming of substances under REACH

([http://reach.jrc.it/docs/guidance\\_document/substance\\_id\\_en.pdf](http://reach.jrc.it/docs/guidance_document/substance_id_en.pdf))

- Manual of Decisions, Criteria for reporting substances for EINECS, Geiss et al. 1992, Vollmer et al. 1998, Rasmussen et al. 1999]

([http://ecb.jrc.it/documents/New-Chemicals/Manual\\_of\\_decisions.pdf](http://ecb.jrc.it/documents/New-Chemicals/Manual_of_decisions.pdf))



# Steptoe REACH Services

STEPTOE & JOHNSON <sup>LLP</sup>

BRUSSELS ■ LONDON ■ WASHINGTON ■ NEW YORK  
CHICAGO ■ PHOENIX ■ LOS ANGELES ■ CENTURY CITY

# Step toe REACH Services - Legal

## Pre-Registration

- ✓ establishing who should Pre-Register
- ✓ establishing what should be Pre-Registered
- ✓ advising on the scope of Registration exemptions
- ✓ advising on overall compliance strategy and implementation
- ✓ acting as “Only Representative”

## SIEF and Pre-SIEF Participation

- ✓ participating in the management/legal affairs committee and general representation
- ✓ acting as “Only Representative”
- ✓ acting as “Third Party Representative”
- ✓ advising and negotiating on data valuation and cost-sharing

## Consortia

- ✓ chairing or participating in management/legal affairs committees

## Legal Agreements

- ✓ consortia
- ✓ confidentiality
- ✓ data licensing
- ✓ cost-sharing
- ✓ lead registrant obligations
- ✓ work with contract laboratories

## Anti-Trust / Competition Law

- ✓ drafting anti-trust policies
- ✓ compliance of contract terms
- ✓ supervising conduct in SIEFs and consortia
- ✓ compliance programmes and training

## Preparation of Registration Dossier

- ✓ preparing arguments supporting the separate submission of hazard data

## Appeals

- ✓ challenging ECHA decisions before the Appeal Board and/or the European Courts of Justice

## Authorisation

- ✓ representing interests in Authorisation procedures

## Ad Hoc Questions

- ✓ responding to strategic, legal, and regulatory questions

## Compliance Training

- ✓ tailor-made training sessions (legal and/or technical aspects)
- ✓ providing briefings on latest developments

# Step toe REACH Services - Technical

## Data Management

- ✓ secure (extranet based) IT system for compliance activities

## Pre-Registration

- ✓ prepare/review inventory
- ✓ assessment of exempted substances, substances to be Pre-Registered, Registered, Authorised
- ✓ reviewing the adequacy of Pre-Registration and required next steps
- ✓ substance identification (“sameness”)
- ✓ submitting the Pre-Registration filing
- ✓ acting as “Only Representative”

## SIEF and Pre-SIEF Participation

- ✓ participating in the technical group/committee
- ✓ acting as “Only Representative”
- ✓ acting as “Third Party Representative”

## Consortia

- ✓ chairing or participating in technical affairs committees

## Preparation of Registration Dossier

- ✓ developing strategies for sourcing data to fill crucial data gaps
- ✓ reviewing the adequacy of Registration activities and required next steps
- ✓ preparing Chemical Safety Assessments and Reports
- ✓ advising on classification and labelling

## Post-Registration

- ✓ responding to questions raised by ECHA or national authorities

## Authorisation


- ✓ supporting Authorisation dossier
- ✓ assisting with socio-economic and alternatives analysis

# Step toe REACH Services

*For additional information, please visit*

*[www.step toe.com/REACH](http://www.step toe.com/REACH)*

*Or click below:*



STEPTOE&JOHNSON LLP REACH SERVICES

**What is REACH?**  
The Regulation (EC) 1907/2006 on Registration, Evaluation and Authorisation of Chemicals (REACH) establishes a new EU chemical 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.