European Commission

(Pre-)registration: Basics

REACH: Final countdown to pre-registration and registration

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Who has to (pre-)register (1)?

- **Manufacturers** of substances and **producers** of articles with intended release:
  - **Each legal entity** (national definition) must register separately
  - May appoint **Third Party Representative**
    - allows keeping identity confidential within SIEF
    - manufacturer remains liable for registration

Who has to (pre-)register (2)?

- **Importers**
  - Same obligations and rights as EU-manufacturers (including right to appoint a Third Party representative)
- However, non-EU manufacturer may appoint **Only Representative** instead
  - In such cases, Only Representatives is **liable** for registration and importer is considered as downstream user
  - Only Representative must submit a **separate (pre-) registration** for every non-EU manufacturer he represents
    - Note that this is a **change** from earlier interpretation!

What to (pre-)register (1)?

- **All substances** manufactured in quantities ≥ 1 tonne/yr
  - **Phase in substances ("existing substances"):**
    - Listed in EINECS
    - Manufactured in the EU but not placed on the market in the EU between 1992 and 2007
    - "No-longer polymers"
    - **Staggered deadlines if pre-registered**
  - **Non-phase in substances (all other substances)**
    - **Registration** before first manufacture or placing on the market
- **Except:** Substances used in food, medicine, radioactive substances, waste, substances listed in Annex IV and V etc.

Types of substances (1)

- **Substances of well defined composition:**
  - **Mono-constituent substances**
    - as a rule of thumb substances in which one main constituent is present to at least 80% w/w **("80% rule")**
  - **Multi-constituent substances**
    - **More than one constituent** is present in a concentration of 10% w/w or more and 80% or less **("<80%/>10% rule")**

⇨ ***Impurities** and **additives** necessary to preserve the stability of the substance do not have to be (pre-)registered separately but are part of the substance*

Multi-constituent substances vs. preparations (1)

Multi-constituent substances

- A multi-consituent substance is the result of a **chemical reaction** in a manufacturing process (typically a reactor)
- One registration ("**reaction mass** of <A> and <B> and... <(constituents >10%>))
- All multi-constituent substances are **phase-in substances** if they or their constituents are listed on EINECS (for practicalities see REACH-IT)

Preparations

- A preparation is gained by mixing two or more substances **without chemical reactions**
- Substances in preparations must be **registered separately** (if not already registered upstream in the supply chain)

Multi-constituent substances vs. preparations (2)

- **Registration of individual constituents of multi-constituent substances possible but only under certain conditions:**
  - **there is no reduction in information requirements**
  - **there is no additional testing as a result**
  - **it leads to more efficient registration (i.e. avoiding numerous registrations)**

⇨ ***However, bear in mind that companies need to agree on substance identity all across Europe***

⇨ ***Going alone might violate data sharing obligations***

Types of substances (2)

- **"UVCB" Substances: Substances of unknown or variable composition, complex reaction products or biological materials:**
  - **Number of constituents is very large or undefinable**
  - **Composition is to a significant part unknown**
  - **Large variability or poor predictability**
  - **Special naming convention for enzymes (IUBMB nomenclature)**

Examples:

EC number	EC Name
296-358-2	Lavender, Lavandula hybrida, ext., acetylated
307-507-9	Lavender, Lavandula latifolia, ext., sulfurized, palladium salt
263-151-3	Fatty acids, coco, reaction products with diethylenetriamine

What to (pre-)register (2)?

- Special rules for:
  - Polymers
    - exempted from registration but monomers contained in them must be registered
  - Intermediates
    - "lighter" registration (lower data requirements)
    - provided that substances are used under strictly controlled conditions
  - Product and process oriented research and development (PPORD)
    - Only notification required
    - Agency may impose conditions

What is the “same” substance?

- Many detailed questions answered in the guidance for identification and naming of substances!
- Be aware that substances may still be the same, even if
  - Composition may vary (e.g. in multi-constituent substances)
  - Impurities may vary (even if this results in different classification and labelling)
- “Sameness” of substance to be decided by registrants in SIEF formation process
  - Companies have a certain flexibility but provision may not be used in an arbitrary way (violation of data sharing obligations)
  - Key question: Does data sharing lead to a meaningful result for all SIEF participants?
  - In case of disagreements on the selection of information opt-out or partial opt-out of joint submission still possible

What happens if companies do not pre-register? (1)

⇨ *Pre-registration is not obligatory but...:*

- In the absence of pre-registration, registration applies from 1 June 2008 (even if companies still may pre-register until 1 December 2008)
- Companies who do not pre-register have to interrupt manufacture, placing on the market and use between 1 June until three weeks after completion of registration during:
  - inquiry
  - submission of registration
  - completeness check by Agency

What happens if companies do not pre-register? (2)

- Companies are still bound by **joint submission** and **data sharing obligations**
  - ☞ If substance has **not yet been pre-registered** at the time of inquiry:
    - participation in SIEF and data sharing is obligatory (as a data holder)
  - ☞ if substance has **already been pre-registered or registered** at the time of inquiry
    - participation in SIEF and data sharing is obligatory
    - opt-out only possible if justified

⇨ ***...if you do not pre-register and (illegally) continue manufacturing, placing on the market or using the substance, you put yourself and your clients at risk!***

What happens after pre-registration?

1. Agency publishes list of pre-registered substances
2. Data holders (downstream users, universities, NGOs etc.) may indicate that they have relevant data on pre-registered substances: they get special role in SIEFs
3. REACH-IT brings submitters of the same identifier together: "Pre-SIEF"
4. Industry needs to agree on SIEF formation
5. Industry needs to share data within the SIEF
6. Industry needs to jointly submit data to Agency via REACH-IT
7. Agency and Member States evaluate data

Where to turn for help?

1. Check the legislation (available in all EU languages) (http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2006:396:SOM:EN:HTML)
2. Check the Guidance website (http://echa.europa.eu)
3. Check the Frequently Asked Questions on the ECHA website (http://echa.europa.eu)
4. Talk to your colleagues, business associations, industry helpdesks
5. Contact your national helpdesk (addresses can be found on http://echa.europa.eu)

Further Information

http://echa.europa.eu

http://ec.europa.eu/enterprise/reach/index_en.htm

http://ec.europa.eu/comm/environment/chemicals/reach.htm

http://ecb.jrc.it/REACH/