



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-constituent substance is the result of a **chemical reaction** in a manufacturing process (typically a reactor)
- One registration (“**reaction mass** of <A> and 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/>

