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# REACH Specifics
# Roles & Responsibility

Outline:
A: Short refreshment on REACH
B: Roles in REACH
C: Responsibility at each role

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This Project is funded by the European Union

Project implemented by Human Dynamics Consortium

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# Recall: Basic principles of REACH

- **Sustainable development**
  - Industry is responsible for safe use of substances
  - Authority controls compliance of industry
  - NGO's must accept marketing of sustainable substances; no phasing-out across the board
- **Priority for data collection**
  - Manufacturing / marketing according to quantity
    - Three categories of priority: 1000 – 100 - 1 tonnes/year
  - Hazardous properties
    - CMR properties (high priority)
    - PBT/vPvB properties > 100 tonnes/year (high priority)
- **Risk management**
  - Communication (CLH and SDS)
  - Authorisation of uses with identified Very High Concern Substances
  - Restriction measures

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# Recall: Scope of REACH

- **Manufactured / imported in Community's territory**
  - Substances as such and in preparation within REACH
    - For intermediates on site/transported separate provisions
  - Cosmetics as end-products excluded from "info into supply chain", but components **not** excluded from registration requirements
- **Substances / components of preparations / certain articles**
  - Excluded are substances in Annex IV ("no-concern")
  - Excluded are categories of substances in Annex V, e.g. substances in nature
    - Minerals, natural gas, liquefied petroleum gas, natural gas condensate, process gases, crude oil: in nature of not chemically modified
    - Other substances in nature if not chemically modified, unless classified as dangerous



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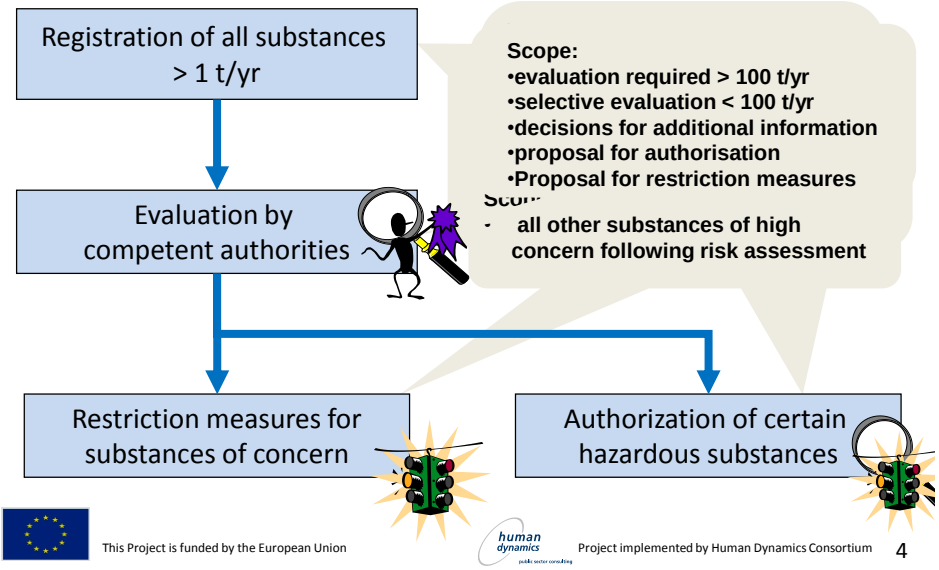
# Recall: Main elements of REACH



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# Roles of a company

**REACH requirements related to activity**

- **Manufacturer** of a substance
- **Importer** of a substance on its own, as component in a preparation, or in an article
- **User (Downstream User e.g. Formulator)** of a substance or preparation (professional)
- **Distributor**, distributive trades
- **Producer** of an article

**Attention: a company may perform several roles**



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# Registration obligation in a REACH-like national legislation prior to joining EU

- **Distinction in phase-in and non phase-in substances**
  - Phase-in ≅ existing substances
  - Non phase-in ≅ new substances

  (Totally dependent on implementation strategy in Accession States)

- **From [starting date] all non phase-in substances to submit registration before manufacturing, importing or placing on the market**

- **For phase-in substances transitional arrangements possible, depending on negotiation with European Commission**
  - Between [starting date] and [deadline] submitting preregistrations
  - Between [starting dates] and [deadlines] submitting registrations depending on volume and hazardous properties

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# Defined in more detail – 1/3?

- **Manufacturer:**
  - Legal entity established within the EU (EEA)/your country producing or extracting substances in the natural state;

    Production = chemical reaction process  Extraction = isolation
- **Importer:**
  - Legal entity established within the EU (EEA)/your country importing a substance on its own or as component in a mixture (= physical introduction into the customs territory of the Community/your country);
- **Placing on the market:**
  - supplying or making available, whether in return for payment or free of charge, to a third party within the EU (EEA)/your country. Import is placing on the market

**NOTE:**
**Distinction between manufacturing as such and manufacturing plus placing on the market**



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# Defined in more detail – 2/3?

- **Downstream User:**
  - Legal entity within the EU (EEA)/your country using a substance, either on its own or in a mixture, in the course of his industrial or professional activities
  - use = any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation
- **Producer of an article:**
  - Legal entity within the EU (EEA)/your country making or assembling an article
  - Article = object composed of one or more substances or mixtures given a specific shape, surface or design.

    (Recent Court decision: Complex article is composed of individual articles)

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# Defined in more detail – 3/3

- **Distributor:**
  - Legal entity within the EU (EEA)/your country, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties

- **Only representative (OR):**
  - Legal entity within the EU (EEA)/your country appointed by a manufacturer, formulator or producer of an article established outside the EU/your country to fulfil the obligations of importers within the EEA/your country
  - An OR might be an importer within the EEA /your country or an independent company with sufficient background in the practical handling of substances and the information related to them to be able to fulfil the obligations of importers



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# Importer according to EU-REACH

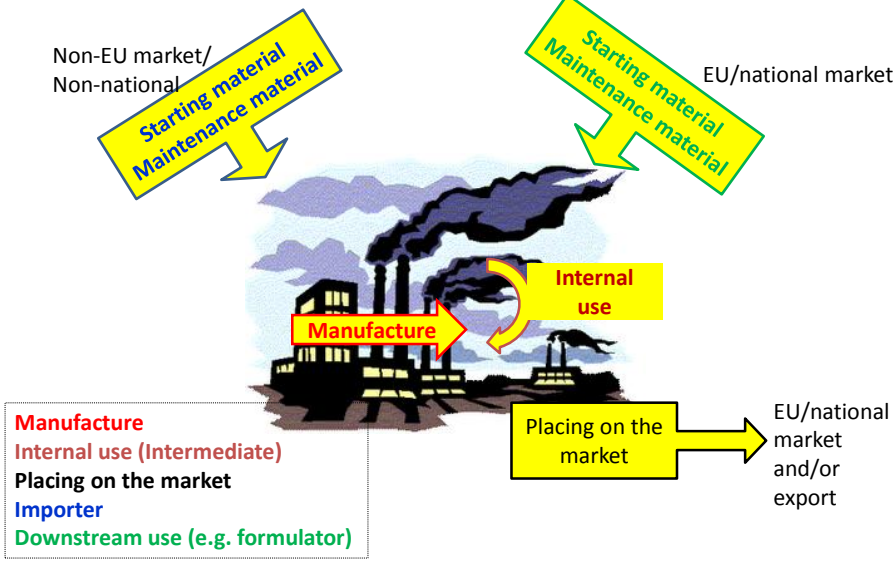

**"Import" means from outside EU/EEA**

**Within EU/EEA is "internal market"**

**EEA (European Economical Area) =**

**EU member states plus Norway, Iceland, Liechtenstein (NOT Switserland)**

## Reminder: Companies always have several roles






## Main tasks depending on each role – 1/2

- **Manufacturer / importer / only representative:**
  - Preregister phase-in (=existing) substances
  - Register substances > 1 tpa within the legally defined deadlines according to volume and hazardous properties
  - Classify & label the substance
  - Draft and distribute (e)SDS in case of substances placed on the market
  - Communicate down the supply chain
- **Downstream user:**
  - Implement recommended risk reduction measures in (e)SDS, or draft a Chemical Safety Report for own use
  - Classify & label formulated mixtures
  - Draft and distribute (e)SDS of formulated mixtures
  - Communicate up the supply chain

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# Main tasks depending on each role – 2/2

- **Producer of an article:**
  - Register a substance > 1 tpa in an article if intended to be released during normal or reasonable forseeable conditions of use, if not registered for that use
  - To submit notification of a substance > 1 tpa in an article being identified as SVHC (listed as candidate for authorisation)
- **Distributor:**
  - Distribute (e)SDSs
  - Communicate up- and down supply chain



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# Tasks in detail for M / I / OR (registrants)

**Responsibility of a manufacturer / importer / only representative is to register a substance within the legal deadlines according to volume and hazardous properties**

- Data required (dependent from quantity range)
  - physical-chemical data
  - (eco)toxicological data
  - emission / exposure data (also for use downstream)
- Chemical Safety Assessment
  - for use/production on site
  - for intended uses downstream

Chemical Safety Report

- Risk reduction measures on site being implemented
- Proposal for additional testing (if > trigger level)
- Proposal C&L

Classification & Labelling

- Safety Data Sheet (SDS)
  - Annexed for intended use(s) exposure scenario(s) and recommended risk reduction measures

Safety Data Sheet

- Communication with downstream users
  - Data on uses downstream from clients

# Tasks in detail for DUs

**Responsibility DUs (= downstream users)**

- **Chemical Safety Report needed ?**
  - Identified uses: actualising M/I CSA (exposure/emission)
  - Not-identified uses: completion of M/I CSA

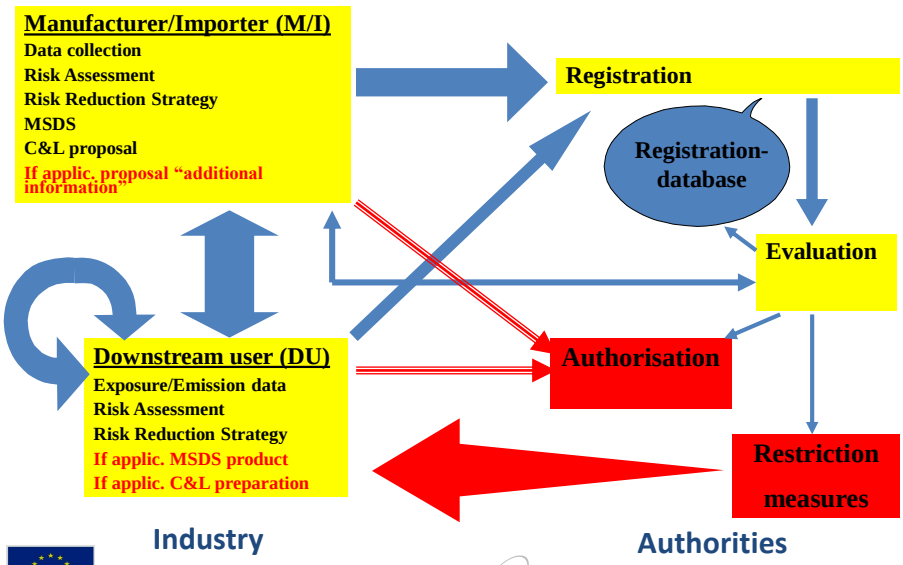
Chemical Safety Report

- **Implementation Risk Reduction Measures on site based on recommended measures from supplier**
- **If applicable, C&L for preparation; SDS for preparation**
- **Communication with downstream users (SDS)**

**Supplementary notification to the Agency in the case of non-identified use(s).**



# REACH system running in practise - simplified: responsibility to industry



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## Pre-registration and exchange of information
## Task for M/I/OR (potential registrants)

**Mandatory data sharing (reason is animal welfare)**

- Non phase-in (=new) substances:
  - Agency involvement for contact between parties
  - If no agreement; Agency involvement as arbiter
    - Compensation; claims lawfully in all Member States
- Phase-in substances:
  - Pre-registration is required
  - SIEF (substances information exchange forum)
  - If no agreement; Agency involvement as arbiter
    - Compensation; claims lawfully in all Member States

**Attention for downstream users:**
- Check listing of your essential substances;
- If not, contact supplier
- If supplier not interested, prepare alternative routes for registration



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# Evaluation by authorities

- **Evaluation based on submitted registrations**
  - Proposals for additional information (high tonnage requirement)
  - Completeness and compliance check of dossiers
  - Substance evaluation based on all information
- **Procedure:**
  - Test proposals: draft decisions by Agency, comments from registrant(s), final decision by MSC / Commission
  - Compliance check: the same procedure
  - Completeness check: decisions by Agency
  - Substance evaluation:
    - Selected by priorities, listed in Community Rolling Action Plan
    - MS rapporteur start evaluation, draft report / decisions, draft opinions from RAC and SEAC, external comments, final decision by MSC / Commission

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# Drafting decisions by authorities

- **Identify substances candidate for authorisation, criteria:**
  - CMR, categories 1 and 2
  - PBT and vPvB
  - Equivalent concern
- **Select substances for authorisation (Annex XIV)**
- **Granting requests for authorisation**
- **Draft Annex XV dossiers for substances of concern**
- **Draft proposals for restrictions in use**



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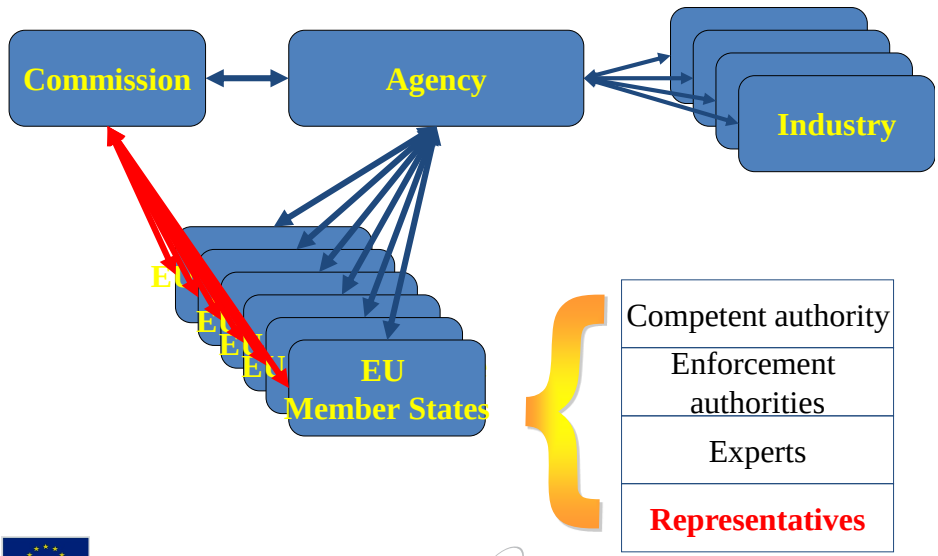
# Organization of EU-REACH



# What companies should do in advance

- Analyse consequences of REACH for their business
- Re-(structure) business organisation and decision-making process
  - Responsibility, centralised decisions, acceptance by hierarchy
- (Re-)organise internal records
  - Total view, including legal status, quick access
- Take stock of their portfolio
  - Manufacturing, importing, directly or via toll-manufacturing
  - Substances, composition of preparations, substances in articles
  - Quantities, uses, need
- Contact suppliers and clients
  - Intensify communication
  - Create awareness of REACH requirements up and down supply chain
  - Guarantee availability of essential products
  - Collect information on use/exposure/emission from own uses
  - Collect information on use/exposure/emission from clients



# Recommendation to companies

- **Organise a network with other business members or trade associations**
- **Establish as business association a "helpdesk" for members**
  - Prepare, develop, use emission scenarios for standardised applications (uses)
- **Intensify communication up and down supply chain**
  - Arrangement for covering CBI issues