

European Commission Enterprise and Industry Directorate-General

European Commission workshop on RIP 3 -Development of REACH Guidance for Industry

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Brief outline of timelines and obligations of industry under REACH

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# Will we reach REACH?

බ REACH is a considerable challenge
බ It covers a very wide range of issues and substances
බ How can guidance help companies?
බ Companies will look for simple guidance
බ Companies will ask us to cover their specific issues in sufficient detail

# How can we reach REACH?

**O**Simple guidance needs to be available

Ofor those with limited experience and capacities (normally also those with limited obligations under REACH)

**Oto give an overview for more experienced users** 

**OIn addition, detailed guidance need to be provided** 

**Ofor those who have more substantial obligations** 

**Ofor those who need specific information** 

# HOW can you reach REACH?

Key steps:

- § Start today with analysing your portfolio of chemicals!
- § Check the scope of obligations
- § Identify your role and tasks under REACH
- § By when do tasks have to be fulfilled?

# **Scope of obligations**

ð REACH applies to the manufacturing, import, placing on the market and use of substances

**§** However, there are exemptions for certain:

- § Substances
- **§ Uses of substances**

§ Reduced obligations for research, product and process related research and development (PPORD) and intermediates

## **Downstream users: Obligations**

- O Downstream users are users of chemical substances that are neither produced nor imported by the company
- **O** Be careful not to overlook that you also may be an importer!
- Key question: Do you receive Safety Data Sheets?
  - ðlf no:

only very limited obligations under REACH

ðlf yes:

apply the risk management measures identified in the SDS

# **Downstream users: Rights**

## **DUs have the right:**

- To make their uses known to manufacturers/importers
- To carry out their own CSA (e.g. for confidentiality reasons)
- To contribute to SIEFs

# Manufacturers/Importers: Registration

- § **Registration for all substances >1 t**
- S Chemical Safety Report (CSR) for all substances >10 t
- ð In the absence of available information, tests may have to be conducted

**O Data sharing (in particular for vertebrate tests)** 

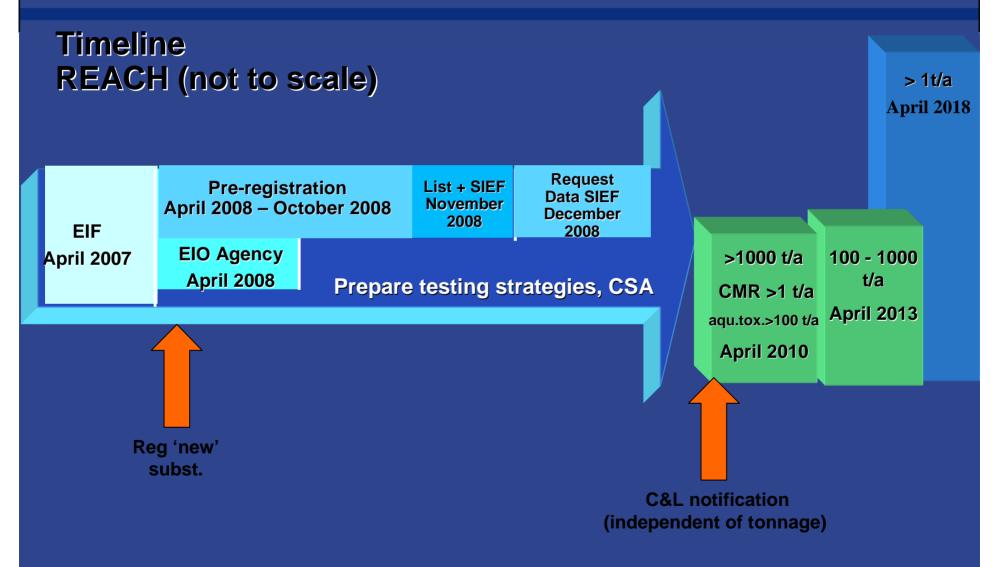
ô Substance Information Exchange Fora (SIEFs)

# Manufacturers/Importers : Registration

### § Timetable:

- Non phase-in substances (neither in EINECS nor already registered): before a substance can be marketed
- Phase in substances: benefit from transition periods <u>if pre-</u> registered
  - Pre-registration: 12 to 18 months after entry into force (except where newly produced/imported)
    - s Identify substance, manufacturer, tonnage band/deadline
    - Agency will publish list
  - Registration: Transition period depending on the tonnage band

# (Pre)Registration



# **Substances in articles**

#### § Registration required if:

- § Substance is intended to be released, and
- **Substance is present in quantities >1 t**

## **§** Notification required if:

- **§ Substance is on candidate list for authorisation**
- § Substance is present in quantities >1 t
- **§** Substance is present in concentration >0.1% by weight

(except where there is no exposure; at the earliest 42 months after entry into force, or 6 months of identification of substance on candidate list)

# **Evaluation**

§ Dossier evaluation: checking completeness and compliance of registration dossiers

§ Substance evaluation: checking whether further information is needed on a substance

# **Authorisation/Restriction**

#### **§** Authorisation: for substances of very high concern

- § Identification of SVHC
- § "Sunset date" by which manufacturing and use is only allowed if it is covered by an authorisation
- § Restriction: only minor changes compared to existing system
  - § Also manufacturing covered
  - **§ Wider range of possible measures**

# Will we reach REACH?

- § Most downstream users and SMEs will have limited obligations
  - õ Simple guidance will be available
  - ô More information will come from manufacturers/importers
- § However, manufacturers/importers will have more significant obligations, depending on:
  - **§ Hazards and risks of substances**
  - **§ Production volume**
  - ô Careful check needed to identify tasks and obligations
  - ô Guidance will assist and can be used to look up details



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# Thank you!