



# *Implications of the REACH Chemicals Regulation on Air Conditioning in Vehicles*

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# Outline

1. Purpose of REACH Regulation
2. Registration
3. Evaluation
4. Restrictions
5. Some specific issues for vehicle air conditioning
6. Conclusions

# 1. A New EU Chemicals Policy

## Registration, Evaluation & Authorisation of Chemicals

- Objective: Sustainable Development
  - Protection of human health and the environment
  - Enhance innovation and competitiveness of EU's business
  - Maintain Internal Market
  - Increased transparency and consumer awareness
  - Integration with international efforts
  - Promotion of non-animal testing
  - Conformity to WTO obligations
- Covers about
  - 27 000 chemical companies
  - 30 000 chemicals

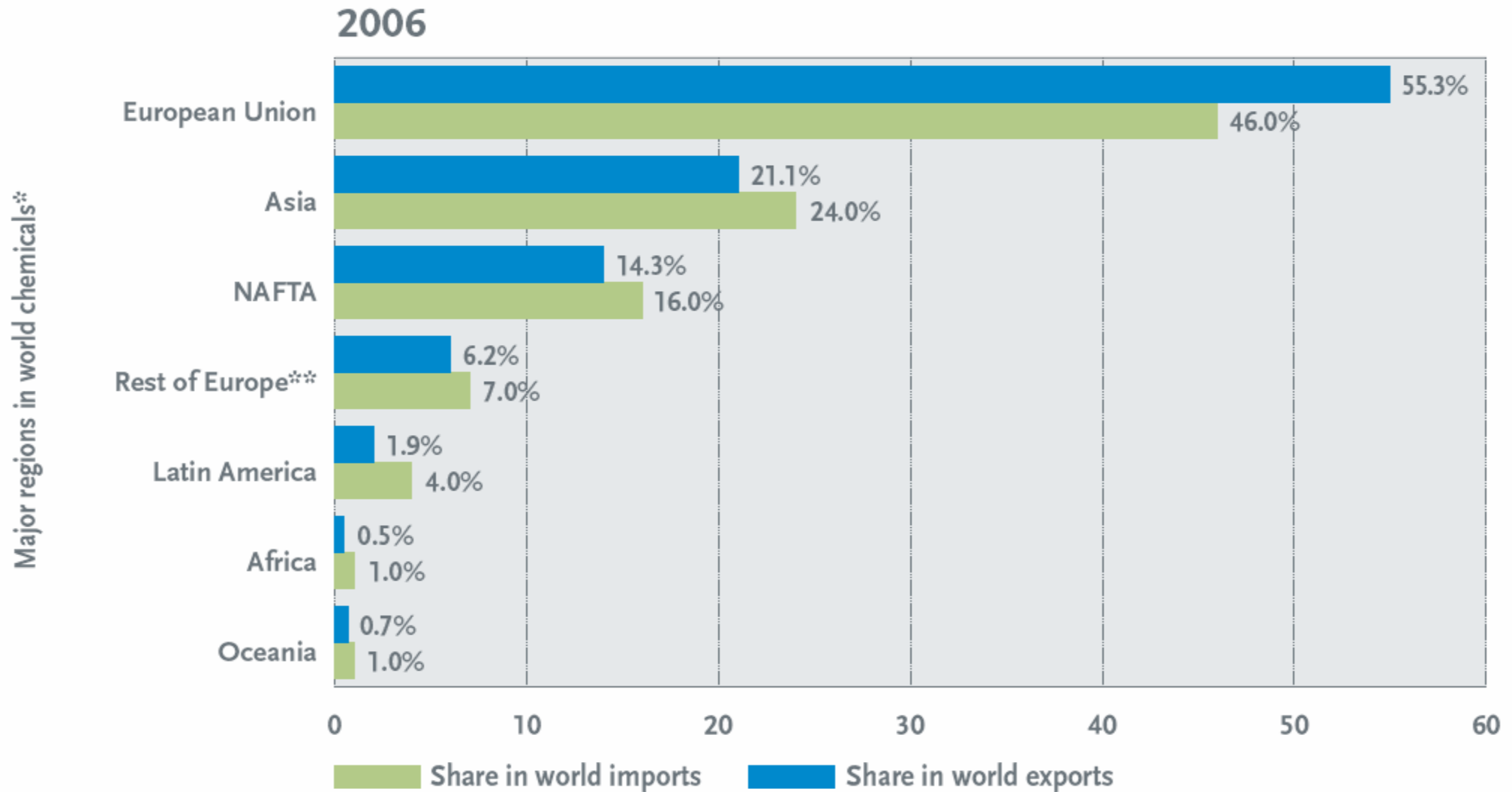
# Key elements of REACH

- Introduces a Single Coherent System for new (non phase-in) and existing (phase-in) substances
- Key elements:
  - **R**egistration by industry of manufactured/imported chemical substances > 1 tonne/year (staggered dead-lines over 11years)
  - Increased information and communication throughout the supply chain
  - **E**valuation of some registered substances (Agency and Member States)
  - **A**uthorisation only for use of substances of very high concern
  - Restrictions: “Safety net” (Community wide action)
  - **C**hemicals Agency to efficiently manage the system

## **Focus on priorities:**

- High volumes (chemicals with greatest likely exposure register first)
- Greatest concern (CMR and R50/53 register first)

# REACH influences global chemicals market: The EU is world's leading trader in chemicals



## 2. Registration: Aim

- Manufacturers and importers obtain information on their substances and
- Use this knowledge to ensure responsible and well-informed management of the risks these substances may present

### Registration Dossier = Documentation

- Technical Dossier: starting at 1 tonnes per year
- Chemical Safety Report: starting at 10 tonnes per year

**No formal acceptance - industry retains responsibility**

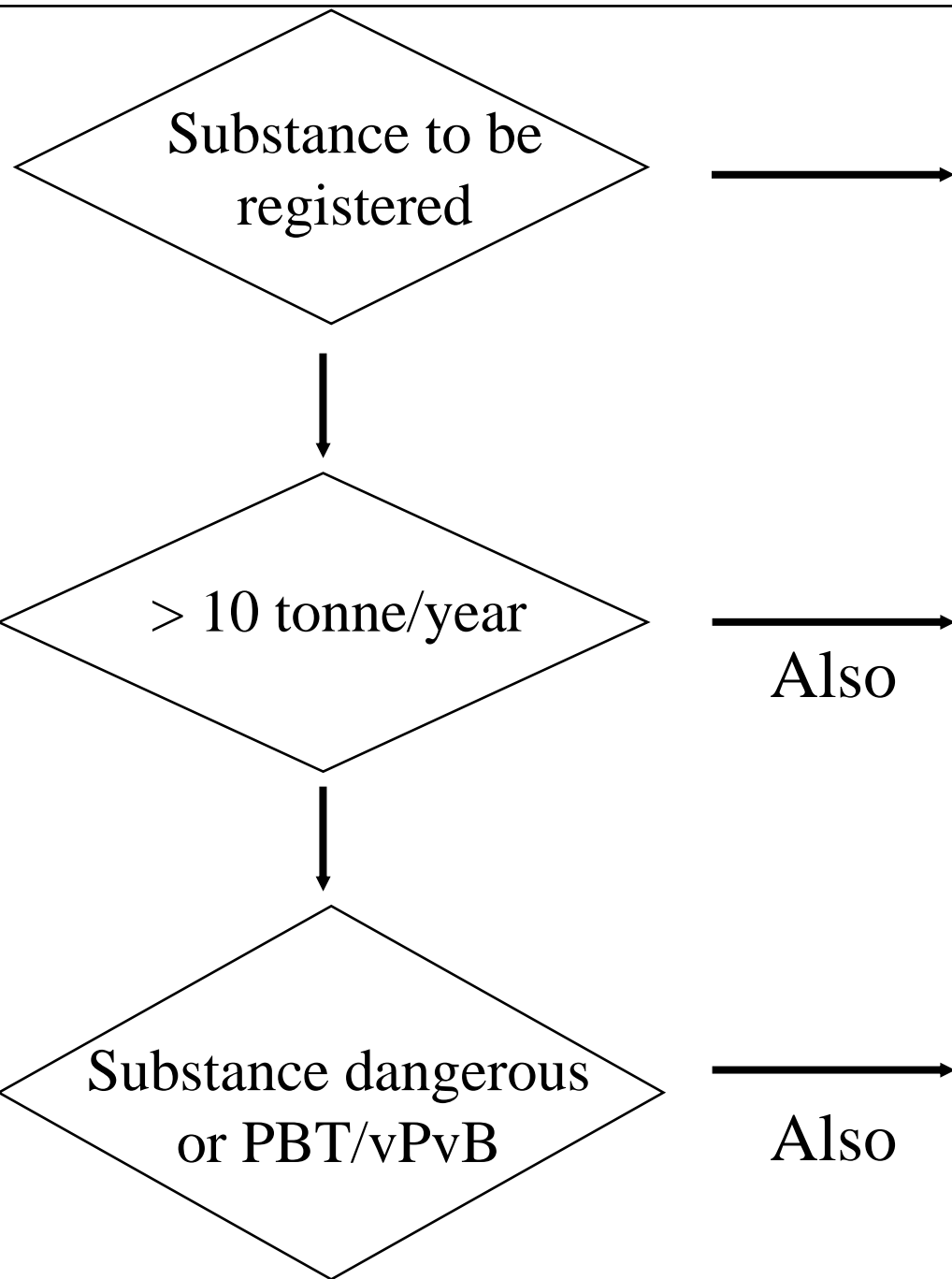
# Who Has to Register?

- Manufacturers and importers.
  - Downstream Users cannot register!
- Producers of articles (in the conditions of Article 7).
- Manufactures of substances outside the EU may appoint an “only representative” to fulfil their REACH obligations.
  - “Only representative” relieves importers of their duties.
  - Importers are then considered Downstream Users.

# What Must Be Registered?

- Registration only concerns substances.....
  - .....on their own, in preparations or in articles
  - Preparations and articles themselves are not registered
  - Only substances manufactured/imported over 1 ton/year
- Exempted from registration
  - Annex IV (well-known substances e.g. water, oils, CO<sub>2</sub>...).
  - R&D
  - Product and Process Oriented Research and Development (but subject to notification)
  - etc.

# Registration dossier - content



## Technical Dossier

- Identify of the manufacturer/importer
- Identity of substance
- Info- manufacture and use of the substance
- Classification and labelling
- Guidance on safe use of the substance
- Study summaries – substance properties
- Test proposals (if relevant)
- Exposure information

## Chemical Safety Report

- Hazard and PBT Assessment

## Chemical Safety Report

- Hazard and PBT Assessment
- Exposure Assessment
- Risk Characterisation AND
- Exposure Scenarios

# Information requirements (inherent properties)

- Physical-chemical properties (e.g. solubility, vapour pressure)
- Toxicity properties (e.g. acute toxicity, irritation, mutagenicity, carcinogenicity)
- Fate properties (e.g. (bio)degradation, partition coefficients)
- Ecotoxicity properties (e.g. toxicity to aquatic or terrestrial organisms)

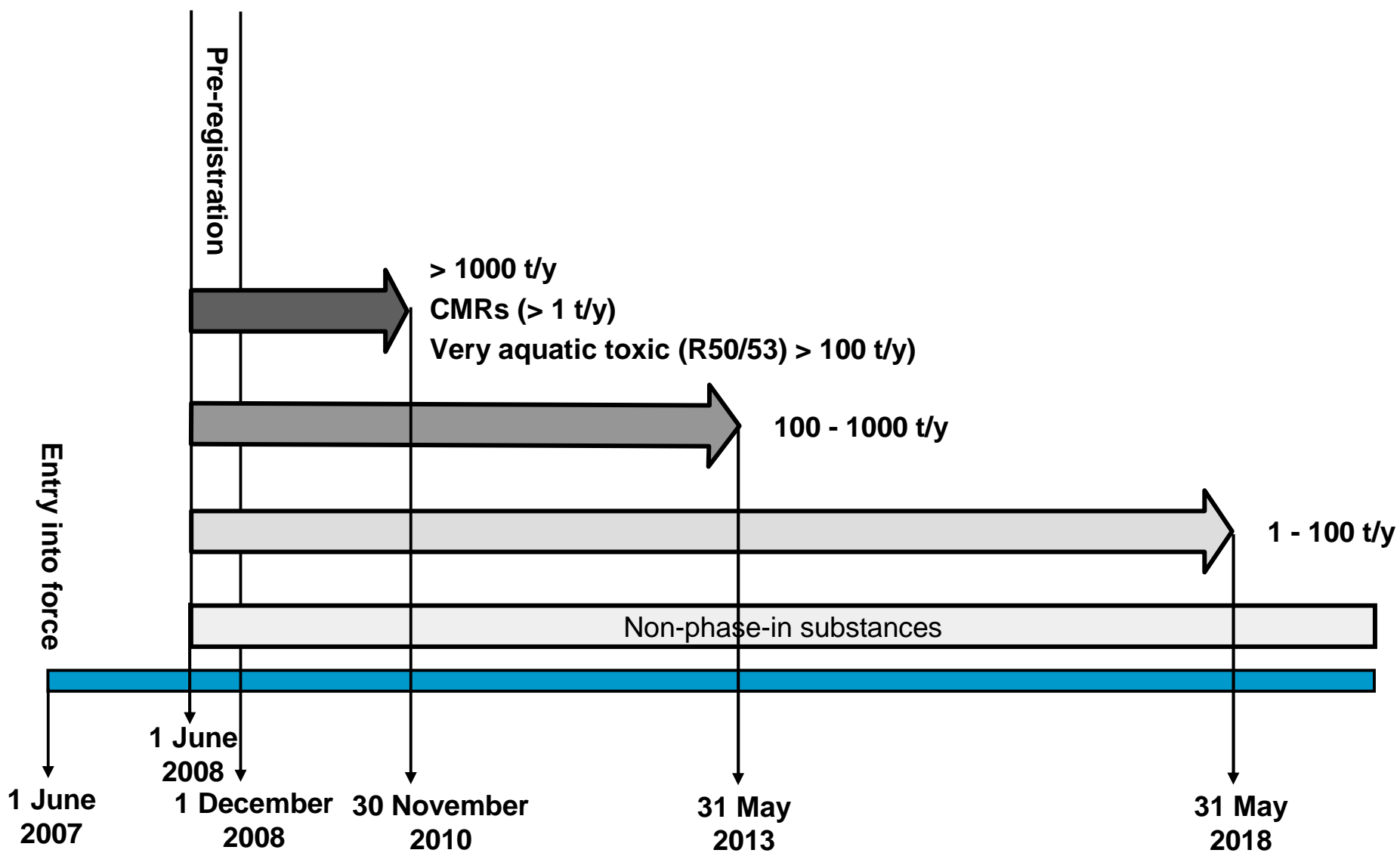
# Use of information in a regulatory context

- Information needs to be adequate for Classification and Labelling and the Chemical Safety Assessment
- Industries' responsibility to decide and justify which further information they consider necessary (starting from a minimum data set)

# Different treatment of “Phase-in” and “non-phase-in” substances

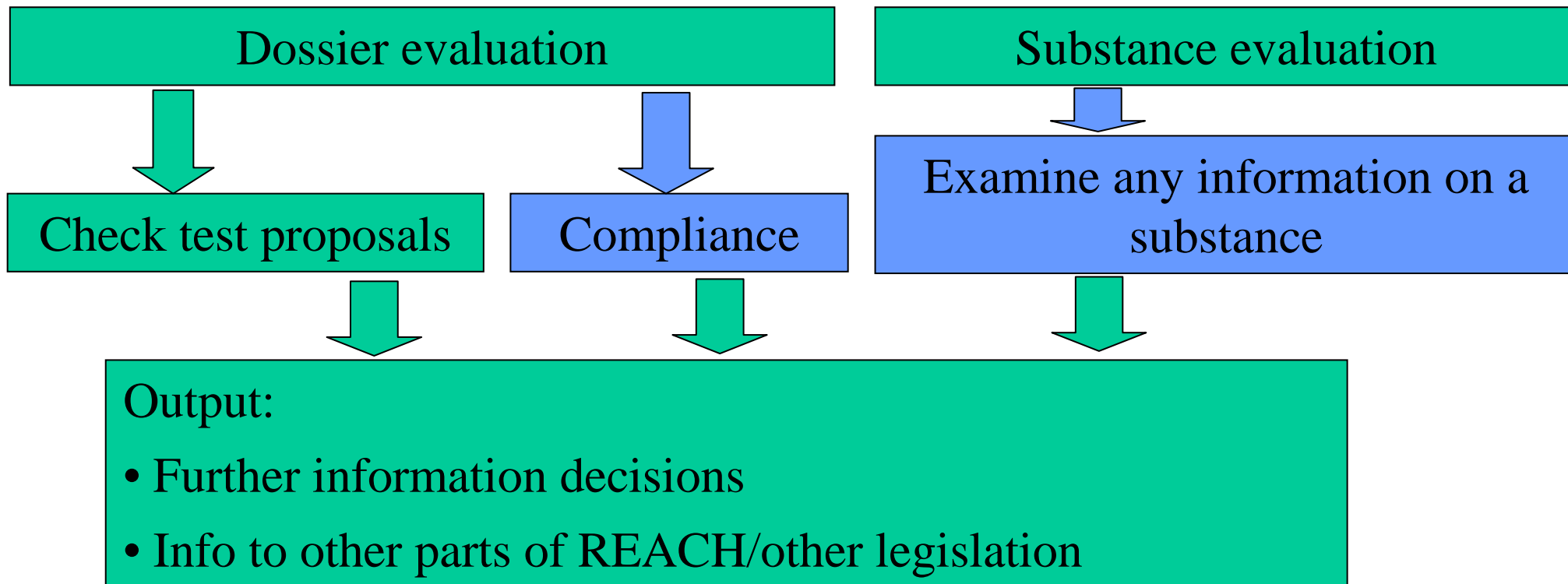
- Phase-in substances:
  - Existing substances – listed on EINECS
  - A few other types: See REACH Article 3(19)
- Non phase-in substances:
  - If not a phase-in substances, i.e. equivalent to ‘new substances’ not yet placed on the market today

# Timelines for Registration



# 3. Evaluation

**Provide confidence that industry is meeting obligations**  
**Prevent unnecessary testing**



# When will the Agency perform a Compliance Check?

- The ECHA may perform a compliance check of any registration dossier.
- Some priority setting is suggested in the legislation:
  - Dossiers where information is submitted separately
  - Dossiers [1, 10t], not full Annex VII (not fulfilling the criteria of Annex III)
  - Substance is on Community Rolling Action Plan (Substance Evaluation)
- Random selection
- **Member States** can communicate with Agency on their needs for compliance check...

# Selection of substances for Substance Evaluation

- The ECHA, in co-operation with MS shall select substances for evaluation, using a risk-based approach.
- When?
- As it is the only possibility to formally request further information...
  - Suspicion of risk?
  - Need for harmonised classification?
  - Is it a substance of very high concern?

# Summary of Evaluation

- Evaluation is the main tool to request further information
- Evaluation should ensure the quality of registration dossier
- Industry responsibility lightens the evaluation process
- Still a task for the Authorities to figure out whether potential for risk (e.g. due to aggregated tonnage)

## 4. Restrictions

- May be applied to:
  - manufacture, use and placing on the market
  - a substance on its own, in a preparation or in an article
- When:
  - an unacceptable risk to human health or the environment
  - the risk needs to be addressed on a Community-wide basis
- Restrictions will be included in Annex XVII
  - takes over existing restrictions of Directive 76/769/EC

## 5. Specific issues for MACs

- R134a and all alternatives need to be registered
  - Exception: R744
- High volumes from at least 2011 onwards (>2000 tonnes)
  - Good to prepare well in advance
- Are alternatives Phase-in (i.e. "existing") or Non-phase-in (i.e. "new") substances?
- Chemical Safety Assessment/Report
  - Information to car manufacturers and system suppliers
- Registration
  - Information to public at large
- Evaluation
  - Dossier evaluation by the ECHA
  - Substance evaluation by Member States
- Restriction, if
  - an unacceptable risk to human health or the environment

## 6. Conclusions

- REACH is a major overhaul of the EU chemicals legislation
- Shift of burden of proof to industry is key
- Major challenges ahead for all stakeholders
- June 1st is 3½ months from now!!!!!!!

# More information

**REACH - European Chemicals Agency: <http://echa.europa.eu.int>**

**ESIS (European chemical Substances Information System): <http://ecb.jrc.it/esis/>**

## Contains

- EINECS (European Inventory of Existing Commercial chemical Substances),
- ELINCS (European List of Notified Chemical Substances)
- NLP (No-Longer Polymers),
- PBT (Persistent, Bioaccumulative, and Toxic) or vPvB (very Persistent and very Bioaccumulative),
- BPD (Biocidal Products Directive) active substances listed on Annex I or IA of Directive 98/8/EC,
- HPVCs (High Production Volume Chemicals) and LPVCs (Low Production Volume Chemicals),
- C&L (Classification and Labelling)
- IUCLID Chemical Data Sheets
- Priority Lists, Risk Assessment process and tracking system in relation to Existing Substances Regulation (ESR).