



REACH and Petrochemicals

Impact on a global Industry

Pierre de Kettenis, ERTC Conference, Brussels, October 2007



Agenda

- Reach objective & requirements
- Timeline for Petrochemicals
- Key milestones
- Scope for Petrochemicals
- Complexity of the sector
- Main challenges
- Impact for petrochemicals
- Steps to pre-registration
- Steps to registration
- Cefic views on REACH
- Joining SIEFS
- Benefits of working with consortia
- Support and useful links

EU Chemicals Policy- REACH

REACH: Registration (> 1 mt/year)
Evaluation (> 100 mt/year)
Authorization (Substances of high-concern)
of “High concern” = CMRs (cat. 1 and 2), PBTs, vPvBs,
Chemicals

- A single regulatory system for new and existing chemicals (replace different pieces of EU Legislation on chemicals)
- Manufacturers and importers of substances
Importer of hazardous substances in preparations/articles
Downstream user, when his application is not covered.
- REACH does not require the registration of preparations, formulations or articles themselves.
- One substance, One registration (data sharing & consortia)

REACH: requirements

- Pre-registration of phase-in substances (existing substances)
 - ✓ Identifies substances and registrants, and facilitates data sharing and joint registration by consortia
 - ✓ No pre-registration will mean: “not on the market”. Substance must be fully registered before manufacture or import may commence
- Registration of substances and their uses by industry
 - ✓ Market access through evidence of risk assessment and risk communication by industry (Chemical Safety Report & SDS)
- Evaluation by authorities includes:
 - ✓ Control of animal testing plan, evaluation of the quality of industry data, estimation of the need for more data
- Authorization of use of certain hazardous products:
 - ✓ Authorization of hazardous substances for specific uses

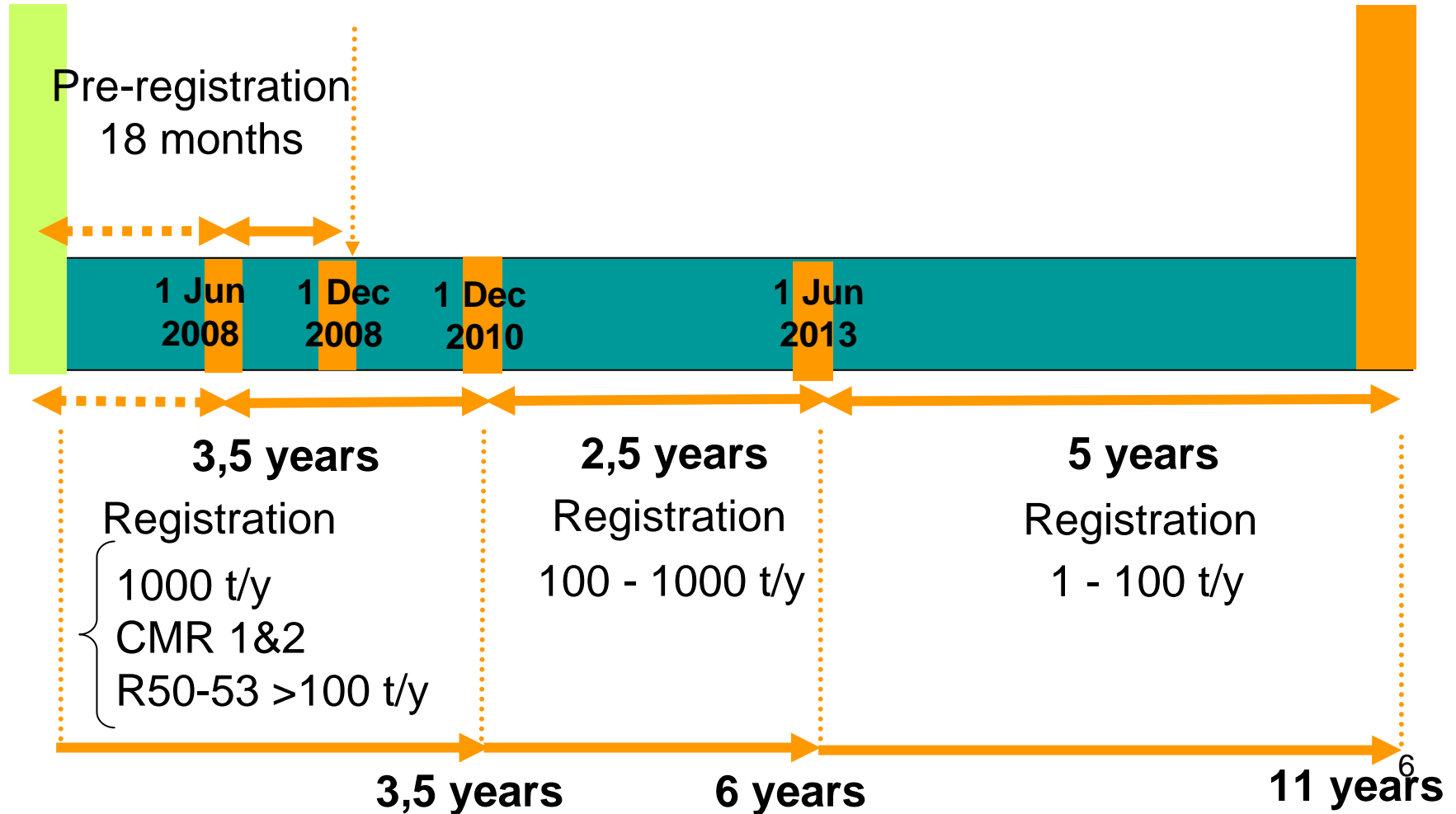
Timeline for Petrochemicals

- REACH is in force since 1st June 2007
- New Central Agency operational 1st June 2008.
- Pre-registration: 1st June 2008 to 1st December 2008
 - ✓ Registrants name, contact details, substance name, registration deadline, tonnage band
- Published pre-registered substances 1st Jan 2009
- Start of Substance Information Exchange Fora (SIEF)
- Registration (>1000T) ends 1st December 2010
 - ✓ Available hazard data (limited for intermediates)
 - ✓ uses and exposure information (if classified substances)
 - ✓ risks assessment and characterization for each use

Key Milestones

1 June 2007: REACH enters into force

1 Jun 2018



Scope for Petrochemicals

- All substances >1T placed on the market
 - ✓ with exception of polymers
- All process intermediates that are isolated
 - ✓ at the end of a process step for use on the same site
 - ✓ Or transported to another unit for processing
 - Limited data sets & Limited testing
 - Conditions of use & transport
- Monomers used to produce polymers (ethylene – butadiene)
 - Full data set including releases and consumer exposures
- Petrochemicals placed on the market as end products
 - Full data set including uses and exposures for each application
 - Consumer exposure data if classified
 - Random evaluation: dispersive uses – substances of concern
 - Authorizations if they contain CMR 1 & 2 or PBT or vPvB

Complexity arising from

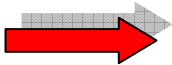
- Petrochemical market

- ✓ Identification of substances placed on the market
 - Lack of consistency in the identification of substances
 - Different CAS # used by companies for similar substances
- ✓ Numerous production sites in a global industry with joint ventures, swaps and toll manufacturing (legal entities?)
- ✓ Numerous traders & importers who must register
- ✓ Overlap between Olefins, Aromatics, HC S and Oil industry
- ✓ Lack of consistency in supported and intended uses
- ✓ Identification inconsistent between Oil and chemical industries

Complexity arising from

- Petrochemical products
 - ✓ Produced from variable crude and feedstock
 - ✓ Intermediates with unknown and variable composition
 - ✓ Complex substances (mixtures) with multiple components
 - ✓ Single CAS# can apply to mixtures with different composition.
 - ✓ Large volumes from start up and shut down out of specs
 - ✓ Substances in processes can be feedstock or output
 - ✓ Grouping inconsistent between Oil and Petrochemicals

Complexity arising from

- Registration process
 - ✓ Substances containing
 - Persistent, Bioaccumulative and Toxic (PBT)
 - Carcinogens, Mutagenic, Reprotoxic (CMR)
 - Classified substances
 -  Chemical Safety Report including
 - Controlled transport conditions
 - Uses and exposure data
 - Consumer exposure data (ex solvents)
 - ✓ Isolated intermediates
 - Escape authorization
 - Do not escape Evaluation & Risk Reduction Measures

Main challenges

- REACH legislation not specific to petrochemicals
 - ✓ Need expertise from the sector
 - ✓ Need to train stakeholders authorities
- CAS# selection and definitions, overlaps, clustering of intermediates and the grouping of substances with variable composition are complex issues and a risk factor
- Evaluation scheme not acceptable for isolated and transported intermediates with substances of high concerns
- Grouping of substances, data sharing, harmonization of product identification and consortia formation is essential to reduce costs and facilitate a consistent implementation

Impact for Petrochemicals

- Around 100 dossiers with full data sets including exposure data
 - ✓ 10% have complete risk assessment dossiers. HPV dossiers did not include exposure data nor intermediates
- Potentially hundreds of dossiers with reduced data sets
 - ✓ (isolated intermediates on site and transported intermediates)
- Each legal entity must register separately each substance.
 - ✓ Registration fee: 24K€ per substance and per legal entity
 - ✓ Authorization fee: 50K€ per authorization.
 - ✓ Issue with legal entities (JV & Toll manufacturing)
- Grouping of substances, data sharing, harmonization of product identification and consortia formation is essential
 - ✓ Registration dossiers 100<n<400
 - ✓ **registration costs 50 M€<x<250M€**

Steps to pre-registration (by 12/2008)

As company, individually, in a association or as a consortium

- Identify all substances under the scope
- Define the border between oils and petrochemicals
- Define the status of substances
 - ✓ Intermediate (isolated or non isolated), end product, transport mode, volume band and main uses.
- Group substances to reduce data requirements
- Perform sameness analysis to reduce use of multiple CAS#
- Identify data requirements and available studies per substance and per category to maximize read across
- Identify legal entities (JV & Toll manufacturing)
- Pre-register between June and December 2008

SIEF formation- process

- Data sharing is an obligation of REACH to reduce animal testing
 - Substance Information Exchange Forum's are defined in REACH
 - Aim: facilitate for the purpose of registration the exchange of information to minimise duplication of tests and to agree on classification and labelling
 - SIEF participants provide others with existing studies, react to requests by others, identify needs for further studies and arrange to carry them out.
 - SIEF composition:
 - All potential registrants (M/I who have submitted the pre-registration information to the Agency for the same substance)
 - All downstream users and third parties who have submitted information to the Agency
- => Operational until 11 years after entry into force

Joining SIEF

- Publication by Agency of list of pre-registered substances (by 01/ 2009)
- Submitters of the same substance are brought together via REACH IT
 - ✓ Members of the pre-SIEF must check if their substance is the same
 - ✓ Agreement on the sameness => **formation of SIEF**
- In general EINECS=SIEF, but
 - ✓ If data do not reflect the properties of substances within one EINECS number => several SIEFs may be formed
 - ✓ If different EINECS numbers reflect the same substance => one SIEF may be formed
- SIEF formation may be organised by a (pre-)SIEF facilitator
 - ✓ First pre-registrant indicating his willingness as SIEF facilitator
 - ✓ May provide other members of (pre-)SIEF with confidentiality agreements, tools to assess the sameness of the substance

It is not allowed to form several SIEFs for the same substance

Joint submission of data

SEPARATELY

Identification of manufacturer or importer

Identification of substance

Information on manufacture and use

For substances 1 to 10 t, exposure information (section 6 of Annex IV)

Indication about review by an assessor

CHOICE

Guidance on safe use (section 5 of Annex IV)

Chemical Safety Report

Indication about review by an assessor

JOINT

Classification and labelling

Study summaries and robust study summaries of information derived from application of Annexes VII to XI

Proposals for testing where listed in Annexes IX and X

Indications about review by an assessor

Industry cooperation – Consortium

Why?

- **To avoid threats on the substance (good quality registration dossier)**
- **To establish a fair financial compensation to data owners**
- **To guarantee an efficient overall process in terms of resources**

How?

- **Contract between the interested parties**
- **Contractual freedom, but under**
 - EU competition law
 - Confidentiality provisions
 - Specific REACH Regulation provisions
- **Consortium is usually created as a « task force »**
- **No separate legal entity**
- **Flexible, limited in time and scope**

Steps in cooperation under REACH

- Get together
 - ✓ Identify and contact Manufacturers/Importers
- Agree on
 - ✓ Substance identity
 - ✓ Rules for cooperation (cost sharing, rights and obligations of members, new members, etc)
 - ✓ Scope of the co-operation (CSR?)
- Get started
 - ✓ Task force management – administration
 - ✓ Sweat equity – allocation of tasks
- Carry out the registration work and submit registration
 - ✓ Data collection
 - ✓ Data gap analysis – waivers – study summaries
 - ✓ Compilation of the common dossier
- Each registrant receives a registration number (licence to market)

Industry support and guidelines

- CEFIC
 - ✓ Reach preparation letters 1 to 5
 - ✓ Trainings and briefings
 - ✓ Technical Guidelines prepared by RIP working groups
 - ✓ REACH Centrum (service unit)
- Association of Petrochemical Producers in Europe
 - ✓ Reach Task Force addressing common issues and harmonize approach.
 - Olefins Sector Group
 - Aromatics Sector Group
 - Hydrocarbon Solvents
 - Coal Chemicals Sector Group
 - Partners: CONCAWE – other trade organisations

Services of ReachCentrum

- Contractual arrangements:
 - ReachCentrum offers tailor made arrangements
- General administration and consulting:
 - Safeguarding transparency and compliance competition law
 - ReachCentrum as a neutral facilitator
- Consortium Management
 - ✓ Pre-Consortium Phase
 - Preparation (Confidentiality, Substance Identification)
 - Formation (Structure, Agreement, Operating Rules)
- Consortium Phase
 - Data Collection & Valuation/Cost sharing
 - Establishment of a Business Plan
 - Management of Preparation and Submission of the Registration Dossier(s)
 - Maintenance of the Consortium Requirements



Cefic views on REACH



- ✓ **Cefic is involved in the legislative process and advocacy to make REACH workable for years**
 - Knowledge of the legislation
 - Extended network within Industry & other relevant stakeholders

- ✓ **REACH will fundamentally change the business of chemistry in Europe**

- ✓ **REACH is now law and we see it as an opportunity**
 - To respond to concerns of society & to regain public confidence and trust
 - To show we really do care and act responsibly, in the spirit of chemical industry's Responsible Care voluntary initiative
 - To demonstrate chemicals are safe

- ✓ **ReachCentrum will support industry in making a success of REACH**

Useful links:

pdk@cefic.be

<http://www.cefic.org>

<http://www.petrochemistry.net>

<http://www.reachcentrum.org>

<http://ec.europa.eu/echa>

<http://reach.jrc.it>

***THANK YOU FOR YOUR
ATTENTION***

BACK UP SLIDES

Olefins: Boundaries

These are the 'big ticket items', this is neither definitive nor restrictive

