REACH
- Registration

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REACH

- **REACH**= **R**egistration, **E**valuation and **A**uthorisation of **Ch**emicals
- New regulation for Chemical Industry
- Greater responsibility to industry to:
  - Provide safety info on substances
  - Manage the risks from chemicals
- Information on safe use to be passed up and down the supply chain

REACH: TIMELINE

- ✓ White Paper (Feb 2001)
- ✓ Stakeholders consultation (summer 03)
- ✓ Commission legislative proposal (Oct 03)
- ✓ EP 1st Reading (Nov 05)
- ✓ Council political agreement (Dec 05)
- ✓ Council Common Position (June 06)
- ✓ Commission communication (July 06)
- ✓ EP 2nd Reading (November 06)
- ✓ Council adoption (December 06)
- ✓ REACH entered into force (June 07)
- ✓ REACH Pre-registration enters into force (June 08)

REACH

- An ambitious scope…
  - From a dual system ("existing" and new substances) to a single regulatory framework
  - from authorities to industry to
    - assess
    - document
    - register
    - and communicate
  - Around 30,000 substances
    - are to be assessed in 11 years!

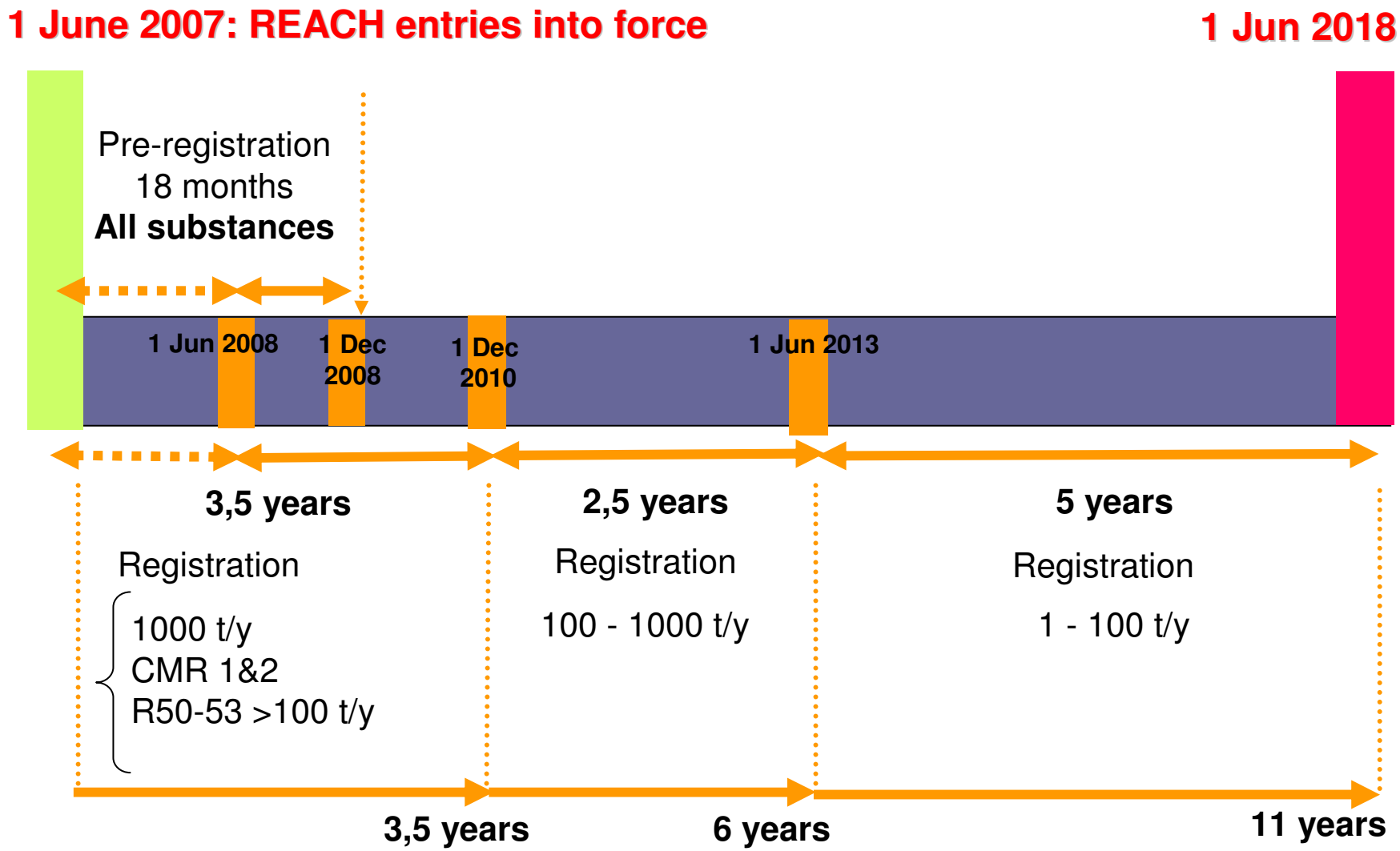
Why REACH?

- To improve the protection of human health and the environment through:
  - Increased knowledge about chemicals.
  - Shifting burden of ensuring safety of chemicals from authorities to chemical operators.
- To increase the competitiveness of the EU chemical industry by:
  - Setting up a single and coherent system for new and existing chemicals.
  - Creating a more favourable environment for R&D activities:
    - R&D up to 1 tonne (instead of 100 kg).
    - PPORD for minimum of 5 years (instead of 1 year).

Overview of industry's main obligations under REACH

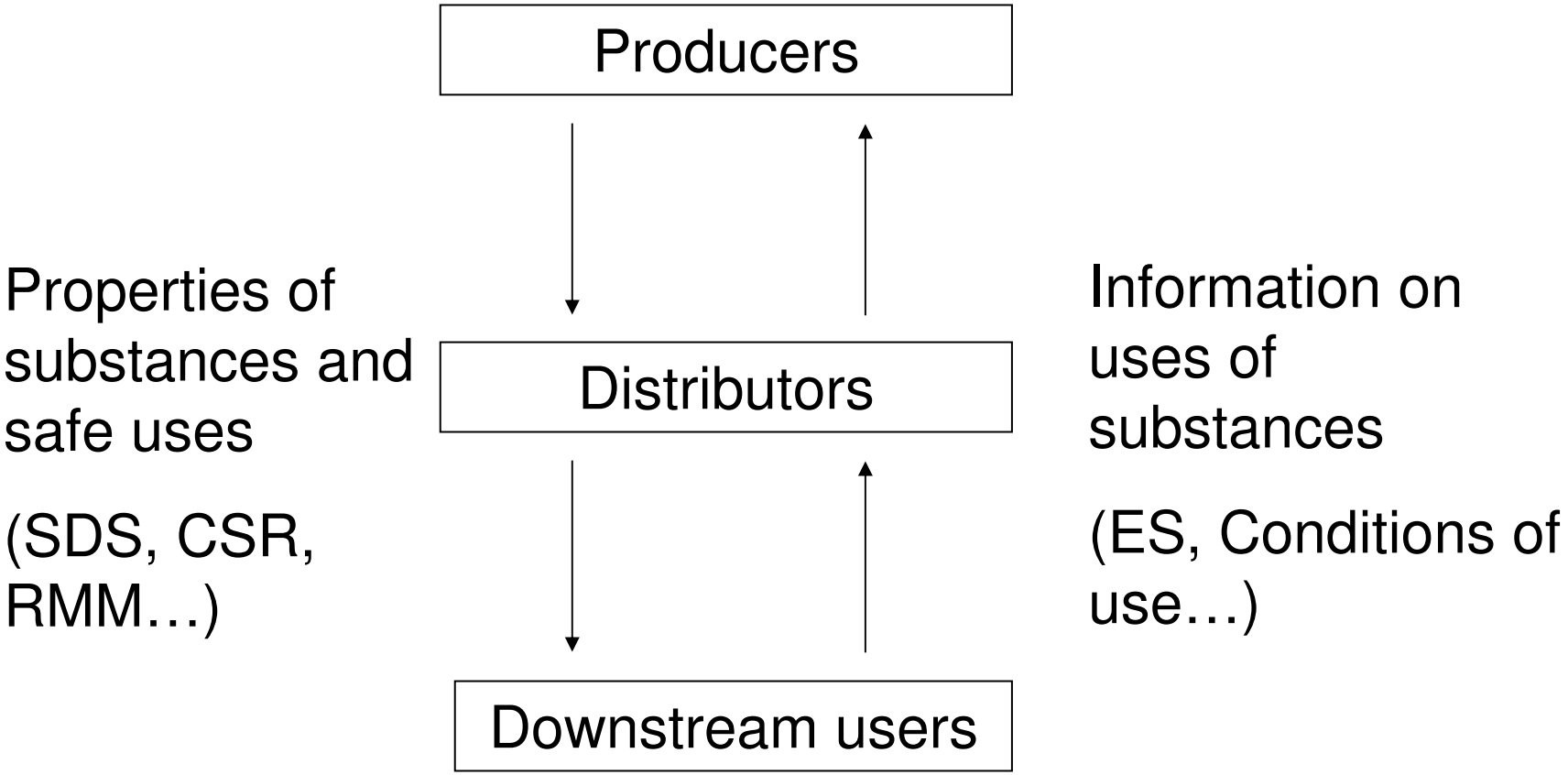
- Producers and Importers:
  - Pre-registration (to benefit from extended registration deadlines)
  - Registration
  - Data Sharing
  - Information in the Supply Chain
  - Preparation of ES for "identified uses"
  - Seeking an Authorisation (for substances in Annex XIV)
  - Compliance with Restrictions
  - Reporting on C&L

Pre-registartion & Registration timetable for phase - in substances



REACH & CHEMICAL DISTRIBUTORS

- REACH will make the chemical distributors play a crucial role in the chemicals supply chain.



. Issues for the REACH Implementation strategy

- REACH Implementation team, with stakeholders from EHS, IT, Purchasing, Marketing & Sales?
- REACH Working plan, with control over the REACH deadlines and necessary REACH Preparation projects to run?
- Substance inventory and reviewed the business needs & potential?
- Cost efficient Registration strategy per substance
- Cost analysis & reviewed the potential cost saver
- Communication strategy upstream & down stream?

1. **The administrative burden under REACH is high. Costs can be significant and may trigger deselection of products due to economic reasons.**

2. **There are opportunities to save costs (grouping, consortia, strategic planning of REACH activities)**

3. **Non-compliance with REACH is not an option as this would be equal with „loss of licence to operate“**

Pre- registration

Pre-registration

Pre-registration: 1 June 2008- 1 December 2008 => info to be sent to the Agency:

- **Name and address of the Importer/ Manufacturer (+ third party representative)**
- **Phase-in substance name & EINECs and CAS No => phase-in substance:**
  - listed in EINECS
  - manufactured in the 15 years before entry into force but not placed on the market
  - "No-Longer Polymer"
- **The envisaged deadline for the registration and tonnage band =>** Art 3.30: volume in calendar year of registration or when M/I for 3 consecutive years, the average of the 3 preceding years. In case legal entity is M and I for same substance, volumes to be added
- **Third party representative**

Pre-registration

- Who can pre-register?
  - EU Manufacturer
  - EU Importer
  - Only Representative of non-EU supplier
  - First time M/I (after 1 June 2007)

- Pre-registration in time: pre-registrant benefit from:
  => transitional registration deadline
  => continue manufacturing/ importing
  => more time to prepare registration

- No pre-registration => substance must be registered as of 1 June 2008 (an inquiry to the Agency and temporary suspension of manufacturing/importing)

Pre-registration information

Data required for pre-registration	
Name(s) in the IUPAC nomenclature or other international chemical name(s)	
Other names (usual name, trade name, abbreviation)	
EINECS number if available and appropriate	
CAS number if available	
CAS name if available	
Other identity code (if available)	
name of the potential registrant	
address	
name of the contact person	
name and address of the third party representative where appropriate	
envisaged deadline for the registration	
Tonnage band	
substance(s) which you intend to use for read-across approach or (Q)SAR[1]	

Pre-registration submission

- Three possibilities:
  - Web based
    - Direct contact with Agency web site
    - Because substance by substance submissions, only for small no of pre-registrations
  - ✓ XML file
  - Use own data system (excel, SAP, HSE etc)
    - Create XML file and submit to Agency
  - ✓ IUCLID 5
    - Will have module to extract pre-registration files (XML)

Registration

Overview

I. Registration : the basic principles

- What?
- Who?
- When?

What Must Be Registered?

- Substances over 1 tonne/year, unless exemption applies.
  - Phase-in substance: volumes are calculated as the average of three (consecutive) years.
  - Preparations and articles are not registered.
    - However, the importer of a preparation must register the substances in the preparation.
      - If more than one preparation imported, the volumes of the same substance in each preparation must be cumulated.
    - Substances in articles also subject to registration/notification under certain conditions.

Exempted from Registration

- Non-isolated intermediates
- R&D
  - PPORD subject to notification.
- Certain substances :
  - Annex IV (well-known substances *e.g.* water, oils, fatty acids, cellulose).
  - Annex V (substance for which registration would be inappropriate, *e.g.* by-products, naturally occurring substances).
- Certain uses : Medicines, food, and feedingstuffs covered by relevant EC legislation.
- Recovered and re-imported substances under certain conditions.
- Polymers
  - However, their components may require registration.
- Specific rules apply to isolated intermediates, articles, and substances regarded as being registered.

Example:

A manufacturer manufactures 100 tonnes of salicylic acid in year X. 50 tonnes are used in medicinal products within the scope of Directive 2001/83/EC on the Community code relating to medicinal products for human use, 50 tonnes are used for the formulation of a non-medicinal preparation. The 50 tonnes used for the formulation of the non-medicinal preparation will be subject to the registration provisions and can, if their properties warrant so, be made subject to authorisation, while the 50 tonnes used in medicinal products are exempted from registration, evaluation and authorisation.

ANNEX IV

Annex IV currently lists 68 substances for which it is understood that sufficient information is available to consider them as causing minimum risk to human health and the environment. These substances are typically of natural origin and the list of exempted substances includes, for example, corn oil and nitrogen (N_2). Substances included in *Annex IV* are exempted from the registration provisions.

Annex IV is under discussion at the moment and will be revised before 1 June.

ANNEX V
EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)

1. *Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight.*

2. *Substances which result from a chemical reaction that occurs incidental to storage of another substance, preparation or article.*

3. *Substances which result from a chemical reaction occurring upon end use of other substances, preparations or articles and which are not themselves manufactured, imported or placed on the market.*

4. *Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:*

   (a) *a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or*

   (b) *a substance solely intended to provide a specific physicochemical characteristic functions as intended.*

5. *By-products, unless they are imported or placed on the market themselves.*

6. *Hydrates of a substance or hydrated ions, formed by association of a substance with water, provided that the substance has been registered by the manufacturer or importer using this exemption.*

7. *The following substances which occur in nature, if they are not chemically modified.*

   Minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas,

natural gas condensate, process gases and components thereof, crude oil, coal, coke.

8. *Substances occurring in nature other than those listed under paragraph 7, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC.*

9. *Basic elemental substances for which hazards and risks are already well known:*

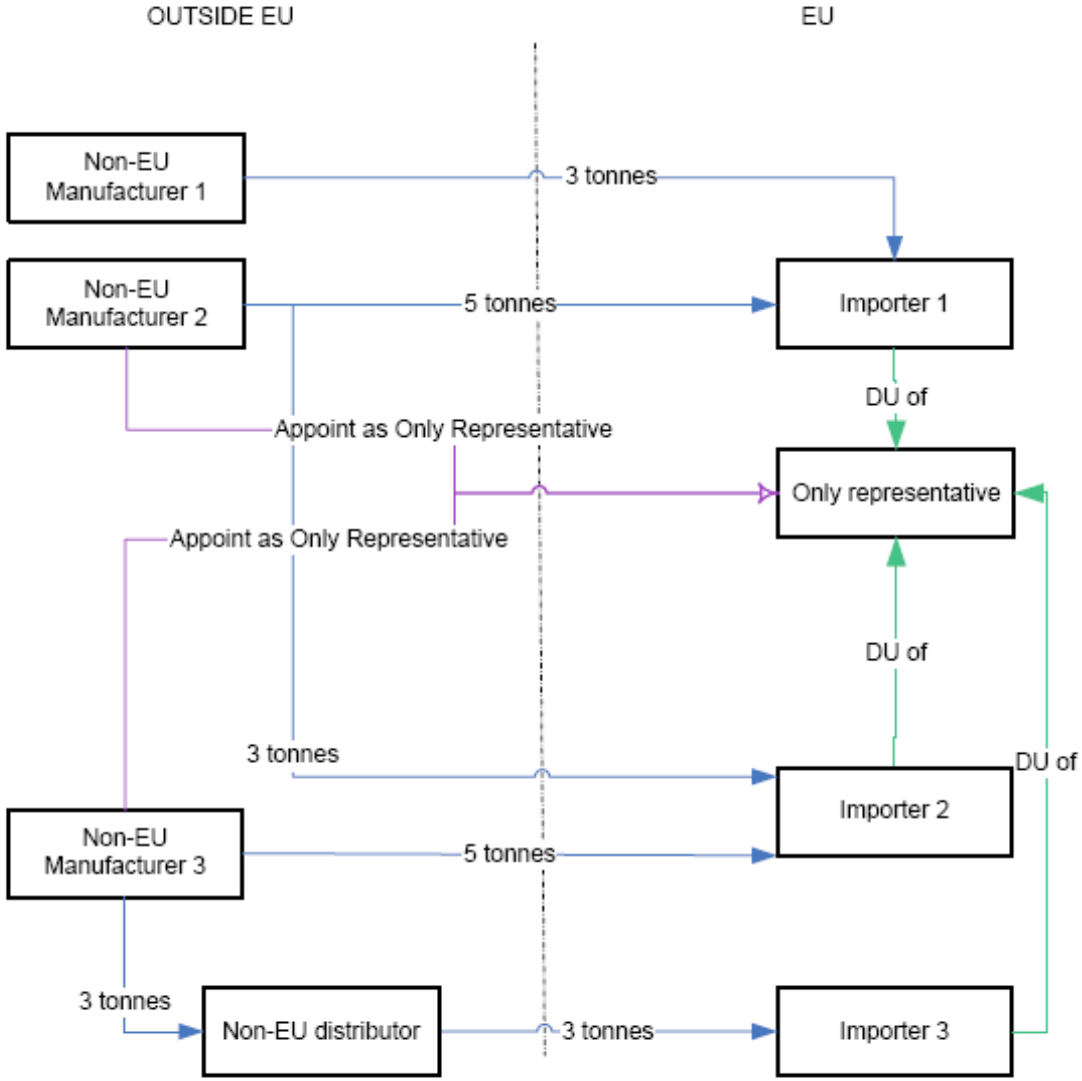
   hydrogen, oxygen, noble gases (argon, helium, neon, xenon), nitrogen.

Annex V is under revision at the moment and will be issued before 1 June

Who Has to Register?

- Manufacturers and importers.
  - DUs may not register.
- Producers of articles (in the conditions of Article 7).
- Manufactures of substances, formulators and article producers outside the EU may appoint an "only representative" to fulfil their REACH obligations.
  - "Only representative" relieves importers of their duties.
  - He must have up to date information on volumes imported and customers.

Example: Role and registration obligations of different actors when an only representative is appointed



Role and Registration obligations

Importer 1
- registers 3 tonnes
- is a downstream user of the only representative for the remaining 5 tonnes

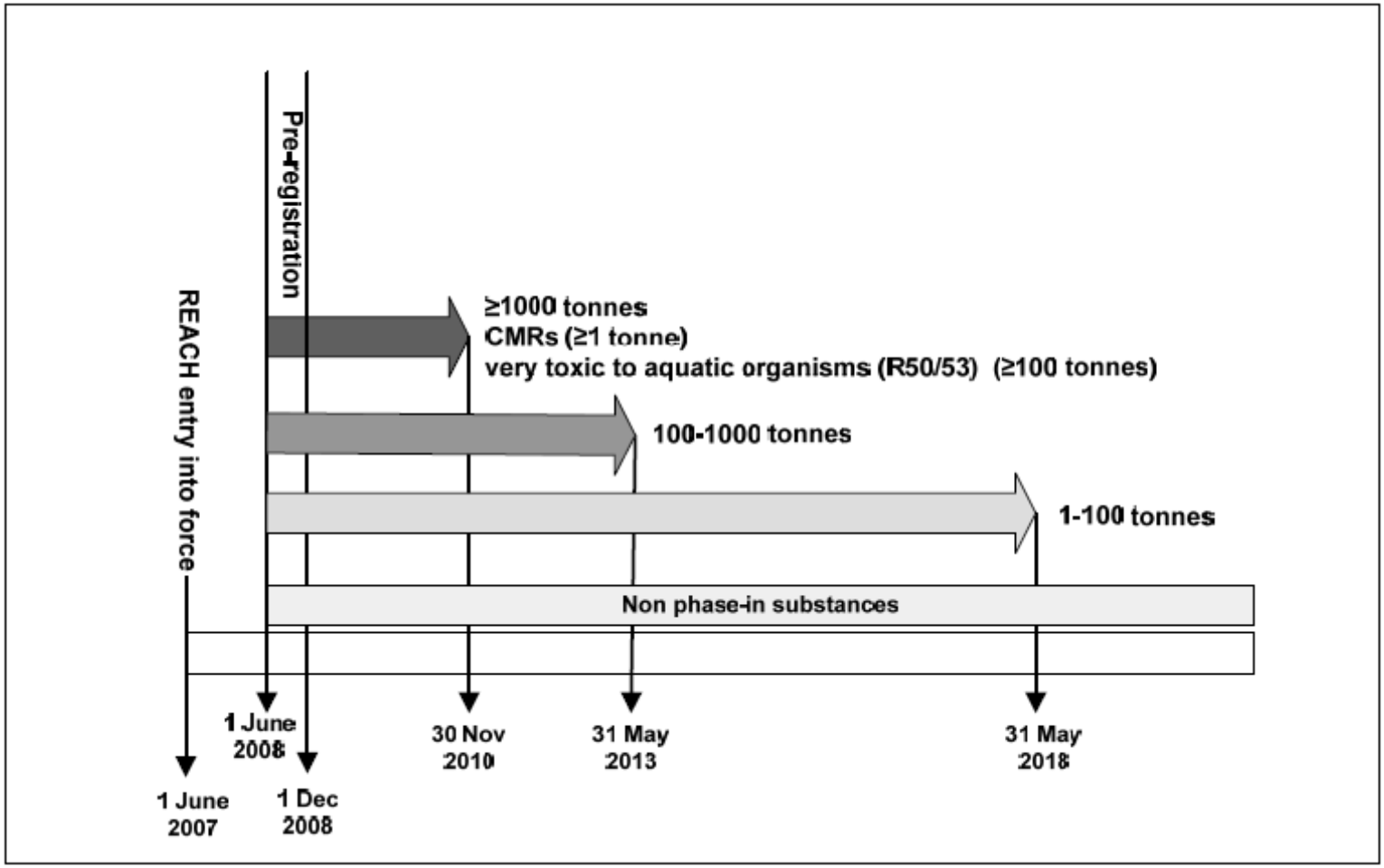
Only representative
- registers the tonnage exported by the non-EU manufacturers 2 and 3, i.e. 16 tonnes of substance.
The registration dossier should be made for 10-100 tonnes, including a CSR.

Importer 2
- does not need to register
- is a DU of the only representative

Importer 3
- does not need to register
- is a DU of the only representative

When to register?

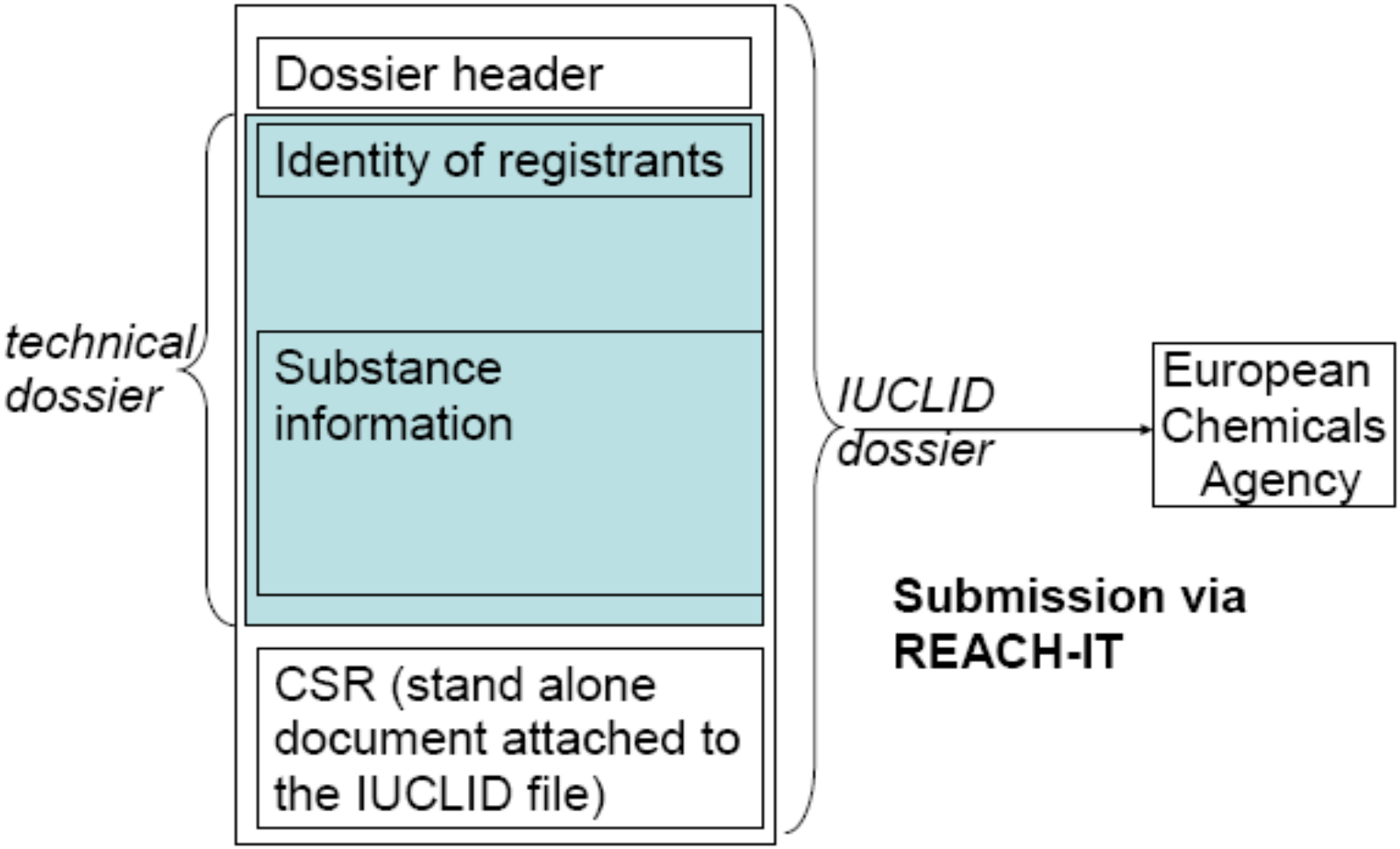
- Obligation to register applies as from 1 June 2008 unless the substance is pre-registered.
- Extended deadlines applied to pre-registered substances:
  - 1 December, 2010
    - CMR 1 and 2
    - very toxic and may cause long-term effects (R50-53) if >100tons/year
    - phase-in substances >1000 tons
  - 1 June 2013
    - phase-in substances >100 tons
  - 1 June 2018
    - phase-in substances > 1 ton

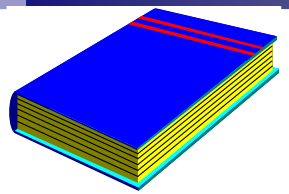

Pre-registration
REACH entry into force
≥1000 tonnes
CMRs (≥1 tonne)
very toxic to aquatic organisms (R50/53) (≥100 tonnes)
100-1000 tonnes
1-100 tonnes
Non phase-in substances
1 June 2007
1 June 2008
1 Dec 2008
30 Nov 2010
31 May 2013
31 May 2018

Information requirements

Information requirements as defined in REACH

Annex VI	General information, C&L, Guidance on safe use, Exposure info for volume 1-10t/y/M,I
Annex VII	Substances in quantities of 1 ton or more
Annex VIII	Substances in quantities of 10 ton or more
Annex IX	Substances in quantities of 100 ton or more
Annex X	Substances in quantities of 1000 ton or more
Annex XI	Adaptations of the standard Testing regime


Dossier header
Identity of registrants
Substance information
CSR (stand alone document attached to the IUCLID file)
technical dossier
IUCLID dossier
European Chemicals Agency
Submission via REACH-IT



Registration dossier

Part 1: Information on the substance

Part 2: Phys-chem, toxicologic. and environmental data

Part 3: Chemical Safety Report

What is the content of Part 1:
Information of the substance **?**
(Annex VI)

Part 1: Information on the substance

Described in Annex VI

Section 1. General Registrant Information

- Registrant ‘s name, address, location of its production site etc…

- In case of consortia, identification of other members of the consortia and part of the registration which apply to other members of the consortium

Part 1: Information on the substance

Section 2. Identification of the substance

- IUPAC name, other names, EINECS/ELINCS #, CAS# and name
- Molecular formula and Molecular weight, info on optical activity
- Purity, nature and % of impurities, nature and % of additives, spectral data (UV, IR, NMR or MS) , HPLC and description of the analytical method

Part 1: Information on the substance

CSR

Section 3. Information on manufacture and use(s) of the substance(s)

- Tonnage manuf. or imported per year for the year of registration
- In case on manuf. , brief description of the technological process
- An indication of tonnage used for his own use(s)
- Form and concentration under which it is made available to DU
- Brief description of the identified use(s)
- Waste quantities and composition resulting from production and identified use(s) (if known)
- Uses advised against

Part 1: Information on the substance

Section 4. Classification and Labelling

- Hazard Classification
- Hazard labelling
- Specific concentration limit (if applicable)

Part 1: Information on the substance

SDS

Section 5. Guidance on safe use of the substance

- Fisrt-aid measures
- Fire-fighting measures
- Accidental release measures
- Handling and storage
- Transport information
- Exposure Controls/Personal Protection
- Stability and reactivity
- Disposal considerations

Annex VI also provides guidance note on how fulfilling the requirements of Part 2 of the registration dossier i.e Phys-chem, Tox. and Environmental data

Step 1: Gather and share all existing information

Step 2: What information is required for the registration
(see Annexes VII-X)

Step 3: Identify information gaps

Step 4: Generate new data or propose the testing strategy

What is the content of Part 2:
phys-chem, tox. and
environmental data
(Annexes VII-X)

Part 2: Phys-chem., tox. and environmental data

1-10t/y:
Annex VII

10-100t/y:
Annex VIII

100-1000t/y:
Annex IX

>1,000t/y:
Annex X

Each testing package
Can be reduced
Based on the general rules for adaptation as described In Annex IX

"Mandatory" package

Negotiable package
depending on the hazard and Exposure of the Substance ->Evaluation by Member States

Information requirements

Physico/chem properties	OECD HPV	REACH t/a
State of substance	+	> 1
Melting/freezing point	+	> 1
Boiling point	+	> 1
Relative density	+	> 1
Vapor pressure	+	> 1
Surface tension		> 1
Water solubility	+	> 1
Partition coeffi. N-octanol/water	+	> 1
Flash point		> 1
Flammability		> 1
Explosive properties		> 1
Self ignition temp		> 1
Oxidising properties	+	> 1
Granulometry		> 1
Stability in org solvents		> 1000
Dissociation const	+	> 1000
Viscosity		> 1000

Information requirements

■Toxicological information	■OECD	■REACH t/a
■Skin irritation		➢1 (in vitro) ➢ 10 (in vivo)
■Eye irritation		➢1 (in vitro) ➢ 10 (in vivo)
■Skin sensitasation		■> 1
■Matagenicity In vitro gene mutation bacteria ■ In vitro cytogenicity ■ In vitro gene mutation mammalin cells ■ In vivo mutagenicity	■+ ■+	➢1 ➢10 ➢10 ➢100
■Acute toxicity	■+ ■+	➢1 (oral) ➢10 (other route)
■Repeated dose toxicity	■+ 28 days	➢10 (28 days ➢100 (90 days) ➢1000 (long term)
■Reproductive toxicity		■> 10
■Reproductive/developmental toxicity	■+	■> 10
■Developmental toxicity		■> 10
■Two generation repro. Toxic		■>10
■Toxicokinetics		■> 10

Information requirements

■Ecotoxicological info	■OECD HPV	■REACH t/a
■Aquatic toxicity short term	■+	■> 1
■Growth inhibition on algae	■+	■> 1
■Short term toxicity fish	■+	■> 10
■Activated sludge respiration		■> 10
■Long term toxicity	■+	■>1
■Ready biodegrability	■+	■> 10
■Ultimate degradation in surface water		■>10
■Soil simulation		■> 10
■Sediment simulation		■> 10
■Abiotic hydrolyses pH	■+	■> 10
■Identification degradation products		■> 100
■Further degradation		■> 100
■Adsorption/desorption screening		■> 10
■Bioconcentration aquatic species		■> 100
■Further studies adsorption/desorption		■> 100
■Further environmental fate and behaviour		■> 1000

Information requirements

■**Ecotoxicological info**	■OECD HPV	■REACH
■Effects on terrestrial organisms (short term)	■+	■> 100
■Effects on terrestrial organisms (long term)		■> 1000
■Long term toxicity sediment organism		■> 1000
■Long term reproductive toxicity to birds		■> 1000

Note: conditions apply for REACH tonnage level requirements

Criteria for waiving or derogation (adaptation) of Testing

(Annex XI)

- ✓**Use of existing Data which are not performed under GLP or not in accordance with Annex V, if adequate**
- ✓**Use of historical Human data , if adequate**
- ✓**Use of Weight of evidence**
- ✓**Use of (Q)SAR (if validated, this can be used to predict presence or absence of effects)**
- ✓**In Vitro Methods (if validated, this can be used to predict presence or absence of effects)**

Criteria for waiving or derogation of Testing (Annex XI)

✓**Grouping of substances and read across approach; broader concept than QSAR; work for ranges of homologous substances (structure, common effects, common metabolism)**

->Test can be done only on one substance and be extrapolated to the others substances of the group

✓**Testing is technically not possible**

✓**Substance-tailored exposure driven testing (only for >100t/y)**

✓**Risk management measures is sufficient to control other potential risks (Annex I)**

Joint submision

Who should submit what?

Registration dossier

Part 1: Information on the substance
- -Section 1: Identity of manufacturer
- -Section 2; Identity of substance
- -Section 3: Information on the manufacturer and use(s) of the substance

Each individual company

Part 1: Information on the substance
- -Section 4: Classification and Labelling

Consortia

Part 1: Information on the substance
- -Section 5: Guidance on safe use of substance

Part 2: Summaries of Phys-chem, tox and environmental data

Part 3: Chemical Safety Report

IUCLID 5

http://ecbwbiu5.jrc.it/

Table 2 IUCLID 5 templates for the registration dossier

IUCLID 5 registration dossiers	Comments
REACH registration 1 – 10 tonnes, physico-chemical requirements	Used in case of stand alone registration or by lead registrant in case of joint registration (see section 8.2.4.1)
REACH registration 1 – 10 tonnes, standard requirements	
REACH registration 10 – 100 tonnes	
REACH registration 100 – 1000 tonnes	
REACH registration above 1000 tonnes	
REACH registration member of a joint submission – general case	Used by members of a joint submission (not the lead registrant) (see section 8.2.4.2)
REACH registration member of a joint submission – intermediates	
REACH registration on-site isolated intermediates above 1 tonne	Used in case of stand alone registration or by lead registrant in case of joint registration (see section 8.2.4.1)
REACH registration transported isolated intermediates 1 – 1000 tonnes	
REACH registration transported isolated intermediates above 1000 tonnes	

Table 3 Relation between information required under Article 10 and the corresponding sections in Annex VI and IUCLID 5 file

Article 10	Annex VI	IUCLID 5
(a) technical dossier		
(i) identity of the manufacturer or importer	Section 1: General registrant information	Legal entity & Section 1.1
(ii) identity of the substance	Section 2: Identification of the substance	Sections 1.1, 1.2, 1.4
(iii) manufacture and use(s) of the substance and if relevant use and exposure categories	Section 3: Information on manufacture and use(s) of the substance(s)	Section 3
(iv) classification and labelling	Section 4: Classification and labelling	Section 2
(v) guidance on safe use	Section 5: Guidance on safe use	Section 11
(vi) study summaries of information derived from the application of Annexes VII to XI		Sections 4, 5, 6 and 7
(vii) robust study summaries of the information derived from the application of Annexes VII to XI if required under Annex I		Sections 4, 5, 6 and 7
(viii) indication regarding the review by an assessor of information submitted under (iii), (iv), (vi), (vii) and (b)		Dossier header 5
(ix) proposals for testing		Sections 4, 5, 6, 7 and dossier header
(x) exposure information for substances in quantities of 1 to 10 tonnes	Section 6: Information on exposure for substances registered in quantities between 1 and 10 tonnes per year per manufacturer or importer	Section 3.5
(xi) request as to which information in Article 119(2) should not be made available on the Internet		All relevant sub sections
(b) Chemical safety report		Attachment in section 13

Confidential information

1. CBI (confidential business information): the data must not be provided to other companies or disseminated to the public.

2. IP (intellectual property): the data should only be provided to other companies when they are trusted (e.g. consortia or with letter of access); the data must not be disseminated to the public.

3. no PA (not public available): the data can be provided to other companies, but must not be disseminated to the public.

RIP 3.10

RIP 3.10
Identification and naming of substances

- Guideline includes naming protocol for:
  - **Well defined substances**
    - Mono constituent
    - Multi constituent
    - Additional phys.-chem. Properties (diamond-grafith)
  - **UVCB substances**

RIP 3.10 - UVCB

Substances of

Unknown or

Variable composition,

Complex reaction products

or

Biological materials

Common features	Examples or representatives	Main identifiers
Well defined substances by chemical composition *[Chapter 4.2.]*	Mono-constituent substances, e.g. - benzene (95%) - nickel (99%) *[Chapter 4.2.1]*	Chemical composition: one main constituent ≥ 80%: - Chemical identity of the main constituent (chemical name, CAS-number, EC-number, etcetera) - Typical concentration and upper and lower limit
	Multi-constituent substances, e.g. defined reaction products like Reaction mass of 2-, 3-, and 4-chlorotoluene (30% each) *[Chapter 4.2.2]*	Chemical composition: a mixture (reaction mass) of main constituents each between ≥10 - <80%: - Chemical identity of each main constituent - Typical concentrations and upper and lower limit for each constituent and for the reaction mass itself
	Substances defined by more than the chemical composition, e.g. Graphite and diamond *[Chapter 4.2.3]*	Chemical composition as mono- or multi-constituent substance AND Other physical or characterisation parameters: e.g. crystallomorphology, (geological) mineral composition, etc.

Common features		Examples or representatives	Main identifiers		
			Source	*Process*	*Other Identifiers*
UVCB substances (Substances of Unknown or Variable composition, Complex reaction products or Biological materials) *[Chapter 4.3]*	Biological materials (B)	Extracts of biological materials e.g. natural fragrances, natural oils, natural dyes and pigments	• Plant or animal species and family • Part of plant/animal	• Extraction • Fractioning, concentrating, isolation, purification, etc. • Derivation*	• Known or generic composition • Chromatographic and other fingerprints • Reference to standards • Colour index
		Complex biological macromolecules e.g. enzymes, proteins, DNA or RNA-fragments, hormones, antibiotics			• Standard enzyme index • Genetic code • Stereo configuration • Physical properties • Function/activity • Structure • Amino acid sequence
		Fermentation products antibiotics, biopolymers, enzyme mixtures, vinasses (products of sugar fermentation) etc.	• Culture medium • Micro-organism applied	• Fermentation • Isolation of products • Purification steps	• Type of products: e.g. antibiotics, biopolymers, proteins etc • Known composition

Common features		Examples or representatives	Main identifiers		
			Source	*Process*	*Other Identifiers*
UVCB substances (Substances of Unknown or Variable composition, Complex reaction products or Biological materials) *[Chapter 4.3]*	Biological materials (B)	Extracts of biological materials e.g. natural fragrances, natural oils, natural dyes and pigments	• Plant or animal species and family • Part of plant/animal	• Extraction • Fractioning, concentrating, isolation, purification, etc. • Derivation*	• Known or generic composition • Chromatographic and other fingerprints • Reference to standards • Colour index
		Complex biological macromolecules e.g. enzymes, proteins, DNA or RNA-fragments, hormones, antibiotics			• Standard enzyme index • Genetic code • Stereo configuration • Physical properties • Function/activity • Structure • Amino acid sequence
		Fermentation products antibiotics, biopolymers, enzyme mixtures, vinasses (products of sugar fermentation) etc.	• Culture medium • Micro-organism applied	• Fermentation • Isolation of products • Purification steps	• Type of products: e.g. antibiotics, biopolymers, proteins etc • Known composition

Thank you