



# From Pre-Registration to SIEF Formation

*What defines a substance to be registered  
and who should act?*

Mike Rasenberg  
European Commission DG JRC  
European Chemicals Bureau



# Agenda



- Introduction
- Scope: which substances?
- Substance identification: fundament of REACH
- Pre-registration and SIEF formation



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# Introduction: entering REACH

- No data, no market (Article 5)
- All substances **imported** and/or **produced** should be registered (Article 6 and 7):
  - $\geq 1$  tpa
  - within scope (*Article 2: Application*)



# Scope and application

- All substances e.g.
  - Polymers\*
  - Monomers
  - Intermediates (with limited exposure potential)
  - R&D substances\*
  - Substances in articles
  - Pesticides\*
  - Biocides\*
  - Human or veterinary drugs\*
  - Food or feeding stuffs\*

## Except

- radioactive substances (Directive 96/29/Euratom)
- substances subject to customs supervision
- non-isolated intermediates;
- carriage of dangerous goods
- Waste (Directive 2006/12/EC)
- Member States may allow for exemptions in the interests of defence.



\* *No need for registration*

– Annex IV (list of substances)

<i>glyceride</i> and SDA Reporting Number: 11-001-00.		
267-007-0	Fatty acids, C <sub>14-18</sub> and C <sub>16-18</sub> -unsaturated., Me esters	67762-26-9
This substance is identified by SDA Substance Name: <i>C<sub>14</sub>-C<sub>18</sub> and C<sub>16</sub>-C<sub>18</sub> unsaturated alkyl carboxylic acid methyl ester</i> and SDA Reporting Number: 04-010-00.		
267-013-3	Fatty acids, C <sub>6-12</sub>	67762-36-1
This substance is identified by SDA Substance Name: <i>C<sub>6</sub>-C<sub>12</sub> alkyl carboxylic acid</i> and SDA Reporting Number: 13-005-00.		
268-099-5	Fatty acids, C <sub>14-22</sub> and C <sub>16-22</sub> unsaturated.	
This substance is identified by SDA Substance Name: <i>C<sub>14</sub>-C<sub>22</sub> and C<sub>16</sub>-C<sub>22</sub> unsaturated alkyl carboxylic acid</i> and SDA Reporting Number: 07-005-00		
268-616-4	Syrups, corn, dehydrated	

– Annex V (list of criteria)

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,



1. New substances under REACH (Article 26)
  - not meaning ELINCS/NONS!
  - not covered in this presentation
  
2. Currently used substances....?



# 'Current' substances

Current coverage	Reference in REACH	Status in REACH	Registration required	Remark
EINECS	Article 3 (20.1)	Phase-in substance	Registration required	"transitional regime" and "further duties"





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"Produced in EU but not marketed"	Article 3 (20.2)	Phase-in substance	Registration required	"transitional regime" and "further duties"



# 'Current' substances

Joint Research Centre

Phase-in substances

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NLP	Article 3 (20.1)	Phase-in substance	Registration required	"transitional regime" and "further duties"
"Produced in EU but not marketed"	Article 3 (20.2)	Phase-in substance	Registration required	"transitional regime" and "further duties"
ELINCS	Article 24	Notified = registered	Considered registered	"further duties"



# Agenda



- Introduction
- Scope: which substances?
- **Substance identification: fundament of REACH**
- Pre-registration and SIEF formation
- How to prepare

## REACH is substances based

- To ensure a properly working REACH system, substance identification is essential;
- Substance identification requires expertise and clear, practical guidance;
- There are different views on how substance identification could (should) be approached ... **but there can only be one solution.**





# REACH definition of "substance":

*Substance* means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.



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Establishment of EINECS – existing chemicals:

- reporting of identity based on “EINECS reporting rules”

1981

Implementation New Substances:

- principle starting point: comparison of identification parameters
- “is the substance covered by EINECS or not?”
- principle decisions in Manual of Decisions

TGD RIP 3.10:

- based on REACH definitions and requirements
- takes over what we learnt from EINECS reporting until now
- combination of current practices

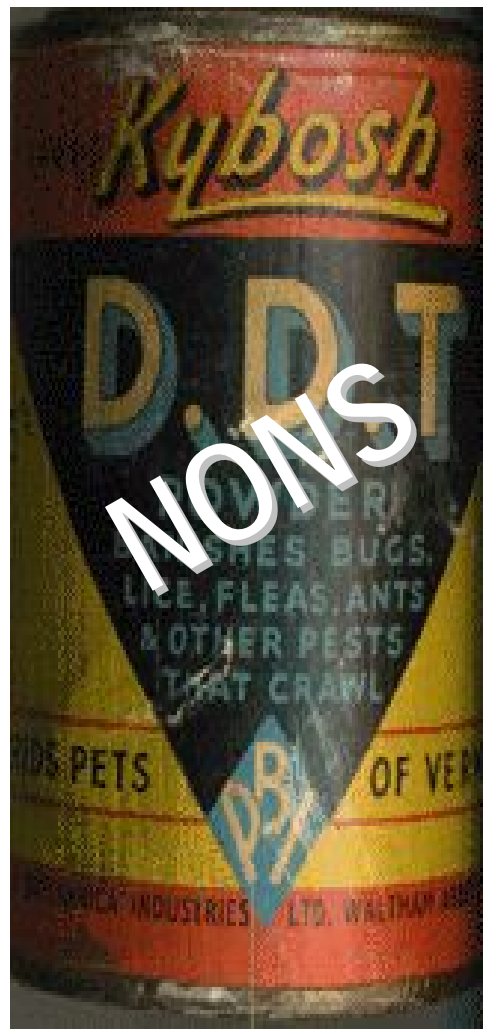
2007

RIP 3.10 was the first RIP finished...

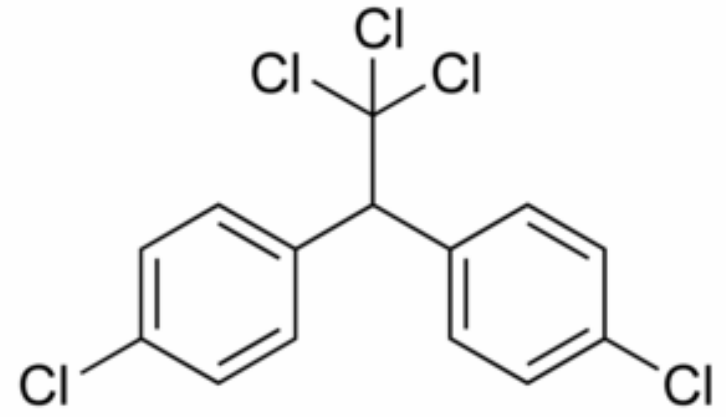


... it was formally endorsed by the Commission (CWG)





# EINECS





# RIP 3.10: basic elements – simplified!

## 1. Well defined substances:

### 1.1 Mono constituent substances (>80%)

1.1.1 chemical identification sufficient

1.1.2 chemical and additional physical identification

### 1.2. Multi constituent substances (>10%)

1.2.1 chemical identification sufficient

1.2.2 chemical and additional physical identification

## 2. UVCB substances (Substances of Unknown or Variable composition, Complex reaction products or Biological materials)



# RIP 3.10: basic elements – simplified!

*Well defined: mono constituent substances:*

<b>Main Const.</b>	<b>%</b>	<b>Impurity</b>	<b>(%)</b>	<b>Name</b>
m-xylene	91%	o-xylene	5	<b>m-xylene</b>
o-xylene	87%	m-xylene	10	<b>o-xylene</b>

# RIP 3.10: basic elements - simplified!

*Well defined: multi constituent substances:*

- Chemical composition: mixture of main constituents each between 10 - 80 %;
- Chemical identity: each main constituent (“mixture of ..”)
- Typical concentrations and ranges

# RIP 3.10: basic elements - simplified!

*Well defined: multi constituent substances:*

- Chemical composition: mixture of main constituents each between 10 - 80 %;
- Chemical identity: each main constituent (“**reaction mass of ...**”)
- Typical concentrations and ranges



## RIP 3.10: basic elements - simplified!

*Well defined: multi constituent substances:*

Main Constituents	Content	Impurity	Content (%)	Name
m-xylene o-xylene	50 45	p-xylene	5	<b>Reaction mass of m-xylene and o-xylene</b>



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Phase-in substances are brought into the REACH system  
via:

- Pre-registration (Article 28)
- SIEF formation (Article 29, 30)
- Joint submission of the registration (Article 11)

Submit the following information to the Agency:

- company and contact information;
- name of the substance, EINECS and CAS number or, if not available, any other identity codes;
- the envisaged deadline for the registration and the tonnage band;
- specification of possible “read-across” substances

Three options:

- on-line data entry
- bulk submission
- IUCLID 5 (under development/under discussion!)

...starting on 1 June 2008 and ending on 1 December 2008.





# Basic elements of SIEF formation

SIEF = Substance Information Exchange Forum

Potential participants are

- Potential registrants, downstream users and third parties who have submitted 'pre-registration' information to the Agency for the *same* substance.
- Registrants/notifiers of the *same* substance within the frame-work of plant protection and biocidal products
- Registrants who have submitted a registration for the *same* phase-in substance before the deadline

The aim of a SIEF is

- to exchange data
- to agree on C&L
- (indirectly) prepare for the Joint submission



Each SIEF shall be operational until 1 June 2018.





## Joint submission for the *same* substance

- One Substance One Registration

## Opt-out possibilities

- disproportionately costly to submit this information jointly; or
- disclosure of information considered to be commercially sensitive (substantial commercial detriment); or
- disagreement with the lead registrant on the selection of this information.



# Joint submission

Joint Research Centre

Information requirement (Article 10)	Lead registrant		Member
	On his own	On behalf of the joint submission	
a (i) the identity of the manufacturer(s) or importer(s)	✓	✗	✓
a (ii) the identity of the substance	✓	✗	✓
a (iii) information on the manufacture and use(s) (incl ES)	✓	✗	✓
a (iv) the classification and labelling	✗	✓	✗
a (v) guidance on safe use	✳	✳	✳
a (vi) study summaries Annexes VII to XI	✗	✓	✗
a (vii) robust study summaries Annexes VII to XI	✗	✓	✗
a (ix) proposals for testing where listed in Annexes IX and X;	✗	✓	✗
a (x) exposure information (1 to 10 tonnes)	✓	✗	✓
(b) chemical safety report	✳	✳	✳

✓ = submits

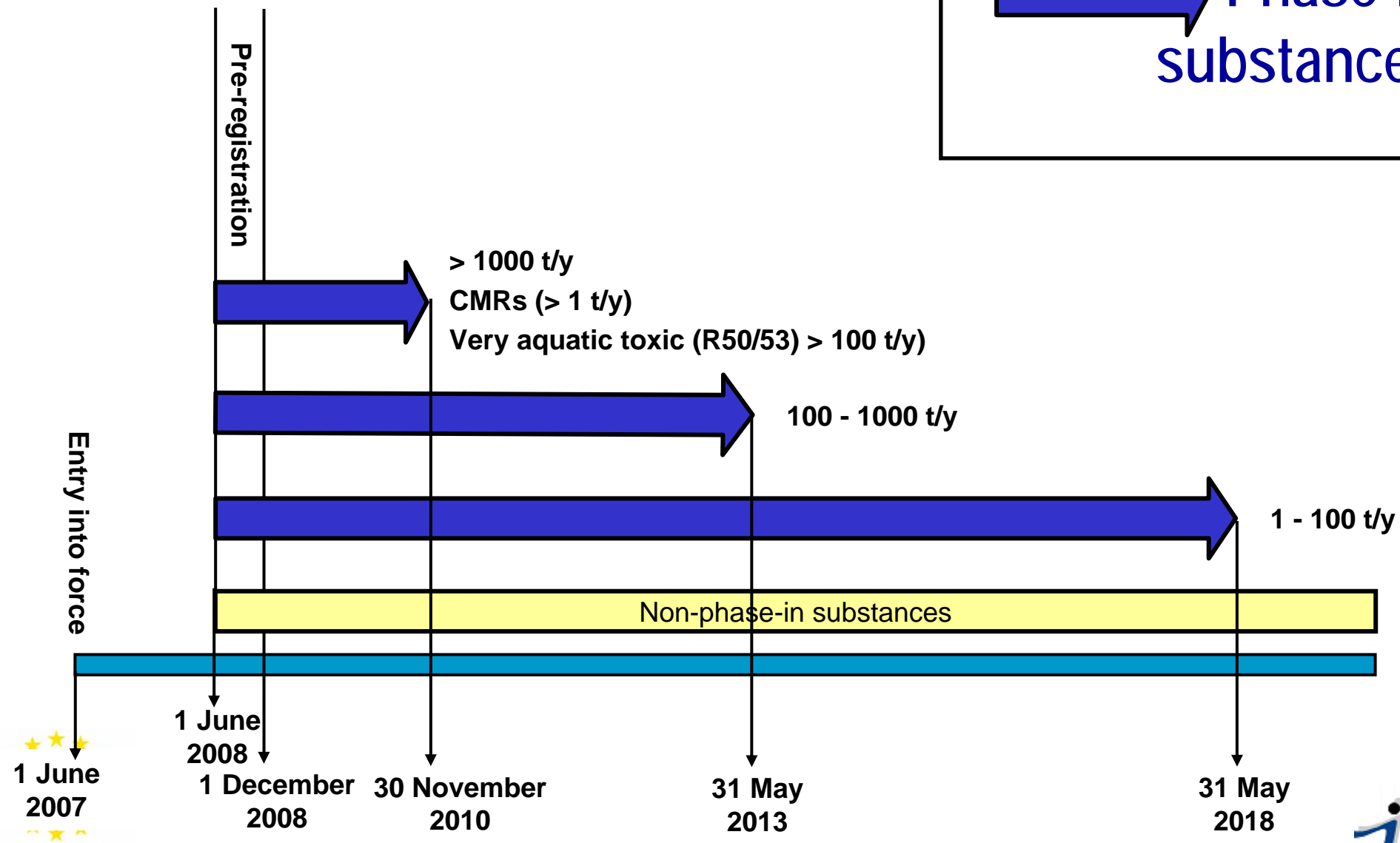
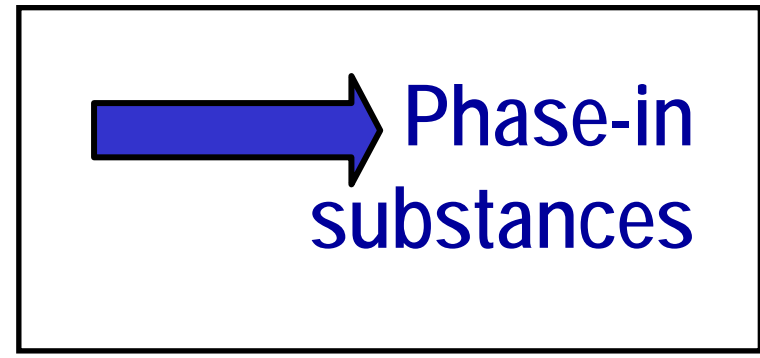
✗ = does not submit

✳ = optional

thp

# Timelines for Registration

Joint Research Centre





# The *same* substance

Starting point: Substance definition (Article 3) and RIP 3.10 guidance.

Well-defined composition: **same name = same substance**

- the same name is in principle sufficient;
- even when certain impurities lead to a different classification/hazard profile.

For UVCB substances: **same name = same substance**

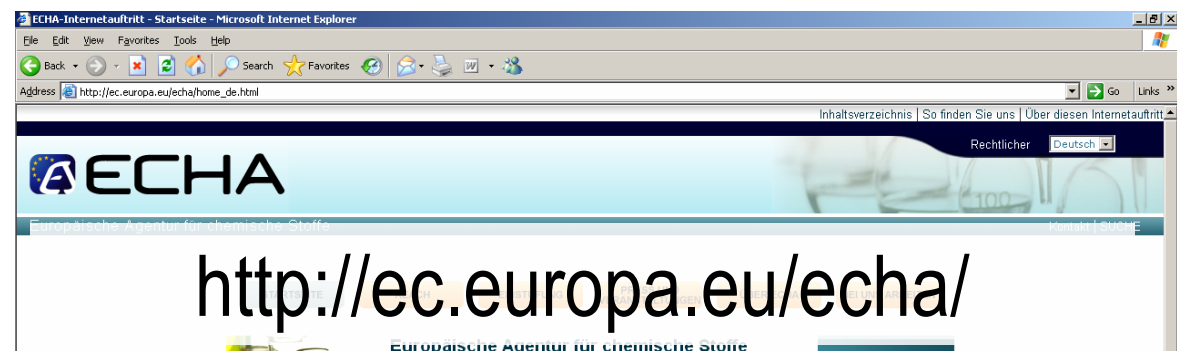
- the same name is in principle sufficient;

*In general: only in cases where (existing) data is clearly not suitable for the other substance the substances can be regarded as different. For instance in case of very different physical properties which have essential impact on the hazard properties, like water solubility.*





- Which of my substances are affected?
- What is my role for these substances
- What is the chemistry of these substances?
- What data do I have available?



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



**Europäische Agentur für chemische Stoffe (ECHA)**

Die Agentur mit Sitz in Helsinki wird die Registrierung und Beschränkung chemischer Stoffe verwalten, um innerhalb der Europäischen Union zu gewährleisten, dass REACH-Verfahren sollen für zusätzliche Informationen sorgen, damit diese sicher verwendet werden und der europäischen Industrie erlauben bietet.

Bei ihren Entscheidungen berücksichtigt die Agentur wissenschaftlichen und technischen Daten sowie so Informationen. Außerdem informiert sie über chemische technische und wissenschaftliche Ratschläge. Sie w Tests bewerten und genehmigen müssen; so kann auf ein Mindestmaß reduziert werden.

Während der ersten zwölf Monate wird die Agentur m und der Einstellung von Personal beschäftigt sein, d Registrierungen ab dem 1. Juni 2008 durchgeführt w

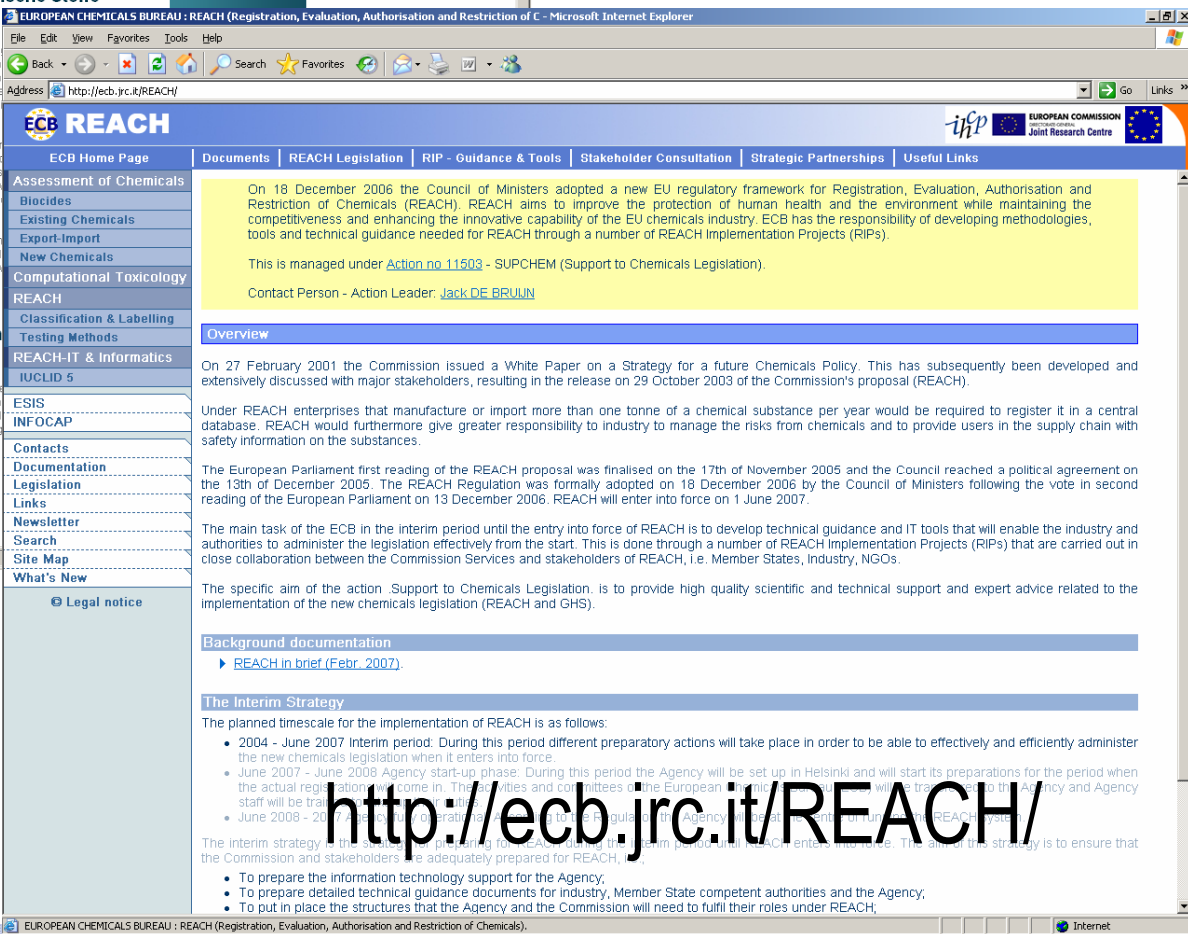
[Mehr dazu](#)

**Was können Sie auf dem Intern ECHA finden?**

Auf diesen Internetseiten sind alle Informationen über zusammengefasst. Sie erhalten hier Zugang zu tech und Antworten (FAQ), Softwareinstrumenten und Her Sie neuste Nachrichten über Leitlinien, Anwendungen und die Verordnung.

[Mehr dazu](#)

Letzte Änderung: 1. Juni 2007



**REACH**

ECB Home Page | Documents | REACH Legislation | RIP - Guidance & Tools | Stakeholder Consultation | Strategic Partnerships | Useful Links

On 18 December 2006 the Council of Ministers adopted a new EU regulatory framework for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). REACH aims to improve the protection of human health and the environment while maintaining the competitiveness and enhancing the innovative capability of the EU chemicals industry. ECB has the responsibility of developing methodologies, tools and technical guidance needed for REACH through a number of REACH Implementation Projects (RIPs).  
This is managed under [Action no 11503](#) - SUPCHEM (Support to Chemicals Legislation).  
Contact Person - Action Leader: [Jack DE BRUJN](#)

**Overview**

On 27 February 2001 the Commission issued a White Paper on a Strategy for a future Chemicals Policy. This has subsequently been developed and extensively discussed with major stakeholders, resulting in the release on 29 October 2003 of the Commission's proposal (REACH).

Under REACH enterprises that manufacture or import more than one tonne of a chemical substance per year would be required to register it in a central database. REACH would furthermore give greater responsibility to industry to manage the risks from chemicals and to provide users in the supply chain with safety information on the substances.

The European Parliament first reading of the REACH proposal was finalised on the 17th of November 2005 and the Council reached a political agreement on the 13th of December 2005. The REACH Regulation was formally adopted on 18 December 2006 by the Council of Ministers following the vote in second reading of the European Parliament on 13 December 2006. REACH will enter into force on 1 June 2007.

The main task of the ECB in the interim period until the entry into force of REACH is to develop technical guidance and IT tools that will enable the industry and authorities to administer the legislation effectively from the start. This is done through a number of REACH Implementation Projects (RIPs) that are carried out in close collaboration between the Commission Services and stakeholders of REACH, i.e. Member States, industry, NGOs.

The specific aim of the action 'Support to Chemicals Legislation: is to provide high quality scientific and technical support and expert advice related to the implementation of the new chemicals legislation (REACH and GHS).

**Background documentation**

▶ [REACH in brief \(Febr. 2007\)](#)

**The Interim Strategy**

The planned timescale for the implementation of REACH is as follows:

- 2004 - June 2007 Interim period: During this period different preparatory actions will take place in order to be able to effectively and efficiently administer the new chemicals legislation when it enters into force.
- June 2007 - June 2008 Agency start-up phase: During this period the Agency will be set up in Helsinki and will start its preparations for the period when the actual regulation will come in. The committees and committees of the European Council will be set up in Helsinki and will start its preparations for the period when the actual regulation will come in. The committees and committees of the European Council will be set up in Helsinki and will start its preparations for the period when the actual regulation will come in.
- June 2008 - 23 June 2009: The period of implementation of the REACH Regulation. The Agency will start its preparations for the period when the actual regulation will come in.

The interim strategy is the result of a preparatory work done by the Commission, industry and NGOs. The aim of this strategy is to ensure that the Commission and stakeholders are adequately prepared for REACH.

- To prepare the information technology support for the Agency,
- To prepare detailed technical guidance documents for industry, Member State competent authorities and the Agency,
- To put in place the structures that the Agency and the Commission will need to fulfil their roles under REACH,

