

A Smithers Group Company

REACH

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Smithers Rapra Technology Ltd



***“possibly the most complex and controversial
piece of legislation in European history”***

EU Commissioner Mr Verheugen

Greenpeace (toxic lobby, 2006)



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Introduction

- Regulation for the EU single market
- European Chemicals Agency (ECHA) in Helsinki
- European Commission & Member State involvement
- Member State enforcement
- Legal text with supporting legislation
- REACH Implementation Projects (RIPs)
- *guidance with legal disclaimer*
- European Court of Justice decisions

REACH responds to three phenomena:

- Lack of data on hazards
e.g. Approx. 65% of 'existing substances' have 'no or limited data'
- Lack of information on use
e.g. no data on migration parameter
average emission values reported
- Lack of correct information/ awareness of chemical safety
e.g. 80% SDS missing or incorrect

Decade of EU chemicals policy 'development'



REACH entered into force on 1 Jun 07



Pre-registration/ registration necessary by 1 Dec 08

'no data, no market'

REACH applies to
substances on their own
substances in preparations
substances in articles

Term 'substance' includes impurities & stabilisers

'Preparation' is a mixture; excludes 'reaction masses' but includes alloys

'Article' is a finished product where shape is more important than chemical composition

Legislation, Guidance, Factsheets
available via European Chemicals Agency (ECHA) website

http://echa.europa.eu/reach_en.asp

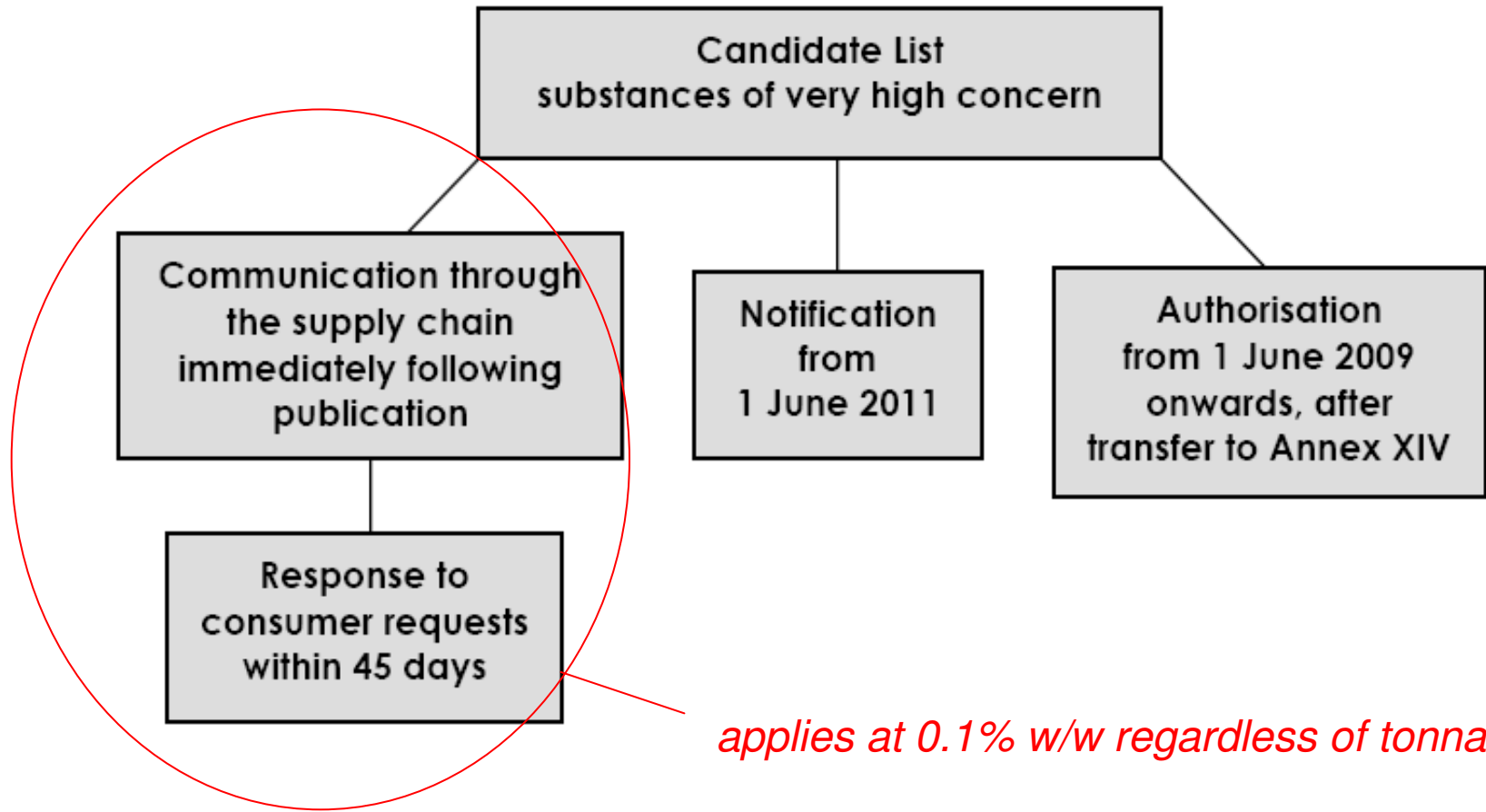
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Fundamentals

- REACH applies per legal entity
 - *i.e. per company*
- Registration is tonnage-dependent
 - *substances equal or above 1 tonne per year*
- Other processes are independent of tonnage
 - *e.g. Restriction, Authorisation*
- Exemptions or Exclusions can apply
 - see REACH Navigator http://reach.jrc.it/navigator_en.htm

Candidate List



applies at 0.1% w/w regardless of tonnage!

Current Draft List – first list due in October

Anthracene

4,4'- Diaminodiphenylmethane

Dibutyl phthalate (DBP)

~~**Cyclododecane**~~

Diarsenic pentaoxide

Diarsenic trioxide

Sodium dichromate, dihydrate

5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)

Bis (2-ethyl(hexyl)phthalate) (DEHP)

Hexabromocyclododecane (HBCDD)

Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins) (SCCPs)

Bis(tributyltin)oxide

Lead hydrogen arsenate

Triethyl arsenate

Benzyl butyl phthalate (BBP)

NGO Campaigns

Date

Dear Sir/Madam

In accordance with the new European regulation on Chemicals, REACH, I am writing to ask you to inform me about the presence in the product XX or its packaging of any chemical from the group of "substances of very high concern" as specified by REACH.

Should any of these substances be present in the product XX or its packaging, I wish to be informed about the name of this substance.

I would be grateful to receive this information within 45 days as required by REACH.

I would also be grateful if you would inform me about steps you are taking to provide products intended for the same use but which do not contain such potentially hazardous chemicals.

Yours faithfully,

SAMPLE LETTER FOR CONSUMER
TO REQUEST INFORMATION ABOUT
SUBSTANCES IN AN ARTICLE.

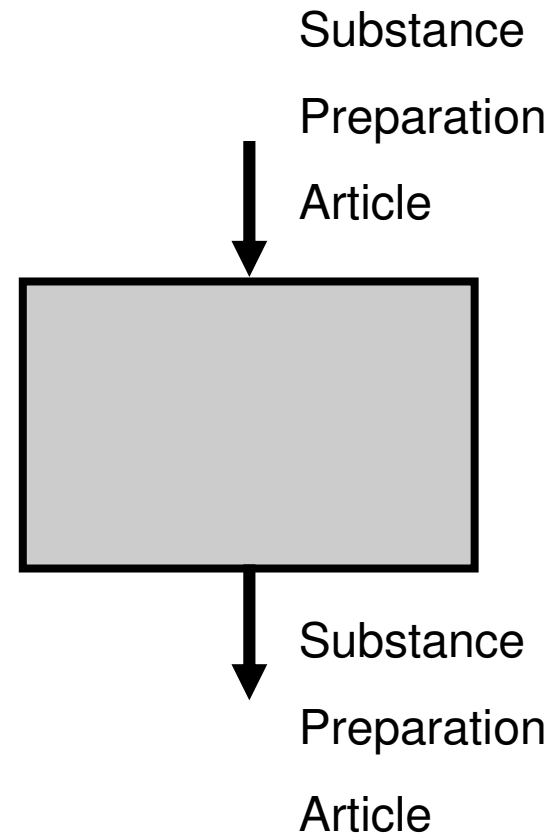
cc: European Chemicals Agency - Helsinki
Annankatu 18, 00120 Helsinki, Finland
www.echa.europa.eu

Your national consumer or environmental organisation

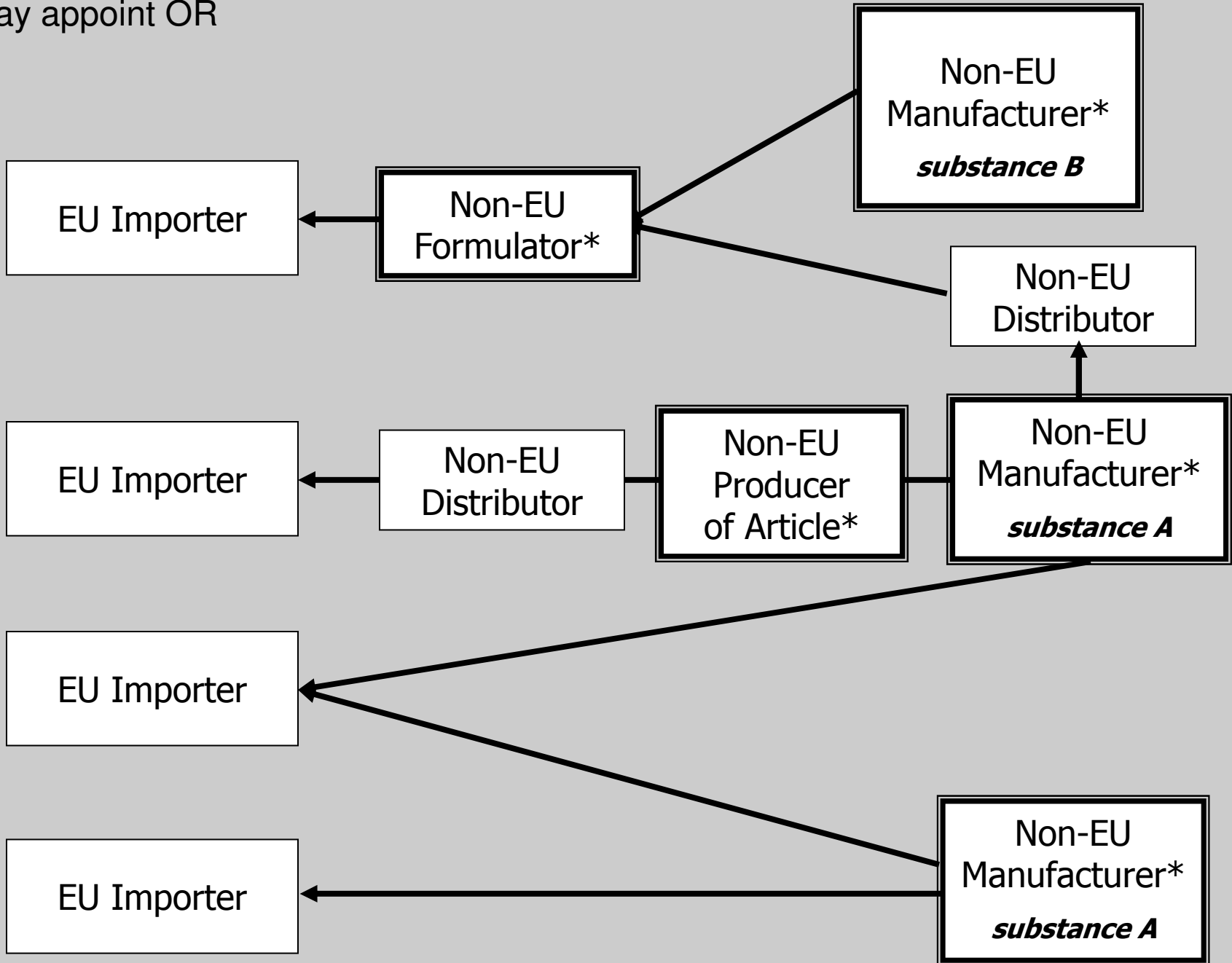


Roles

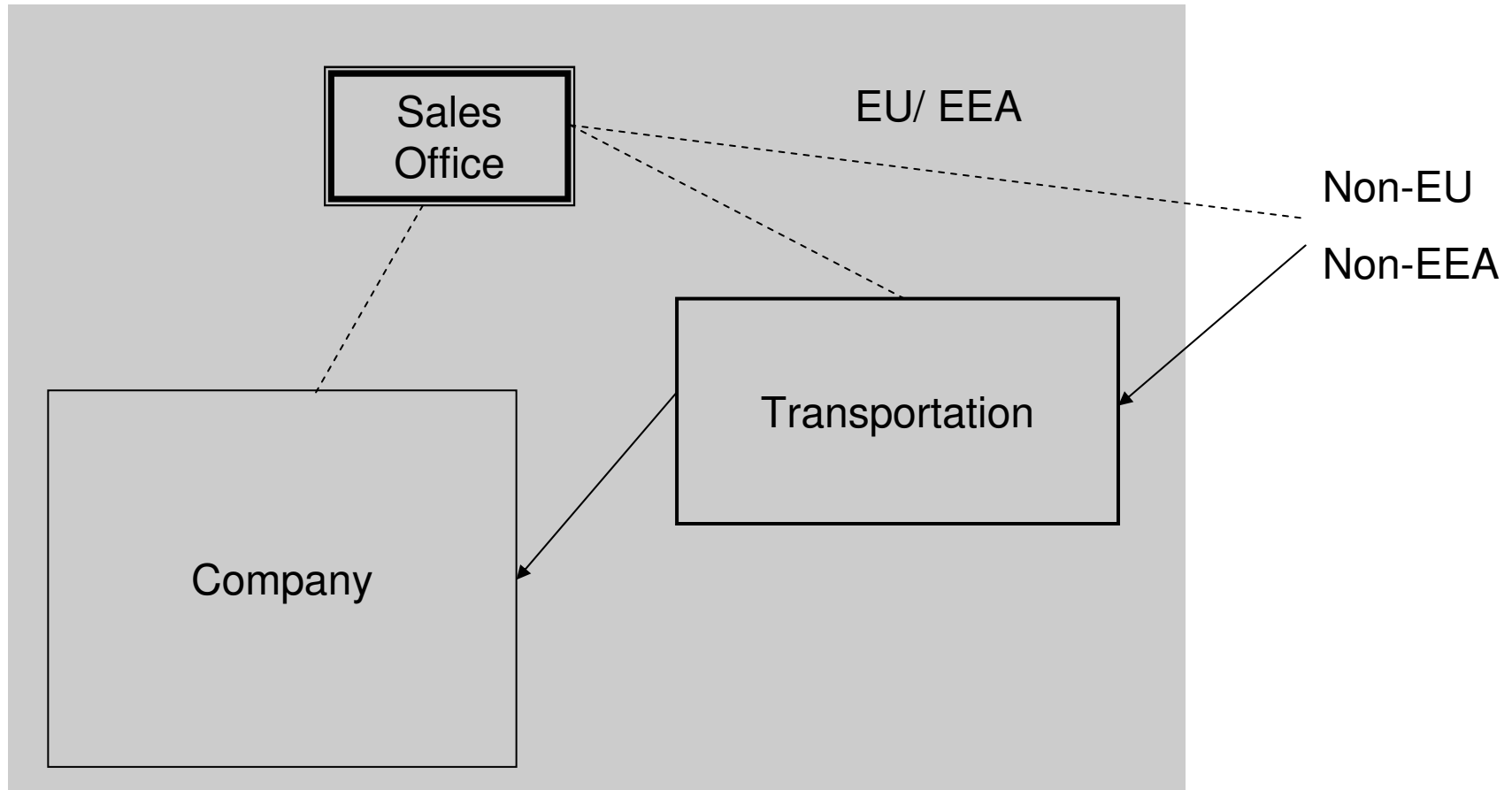
- Manufacturer
- Importer
- Producer of an article
- Importer of an article
- Downstream user
- Distributor (including retailer)
- Only Representative



* may appoint OR



Importer?



Registration: manufacture

Substance

Substance registration if ≥ 1 tonne per year

Substance in
preparation

Substance registration for each substance ≥ 1 tpy

Substance intended to be
released from an article

***Substance registration for each substance ≥ 1 tpy
(unless 'use' already registered)***

Registration: import

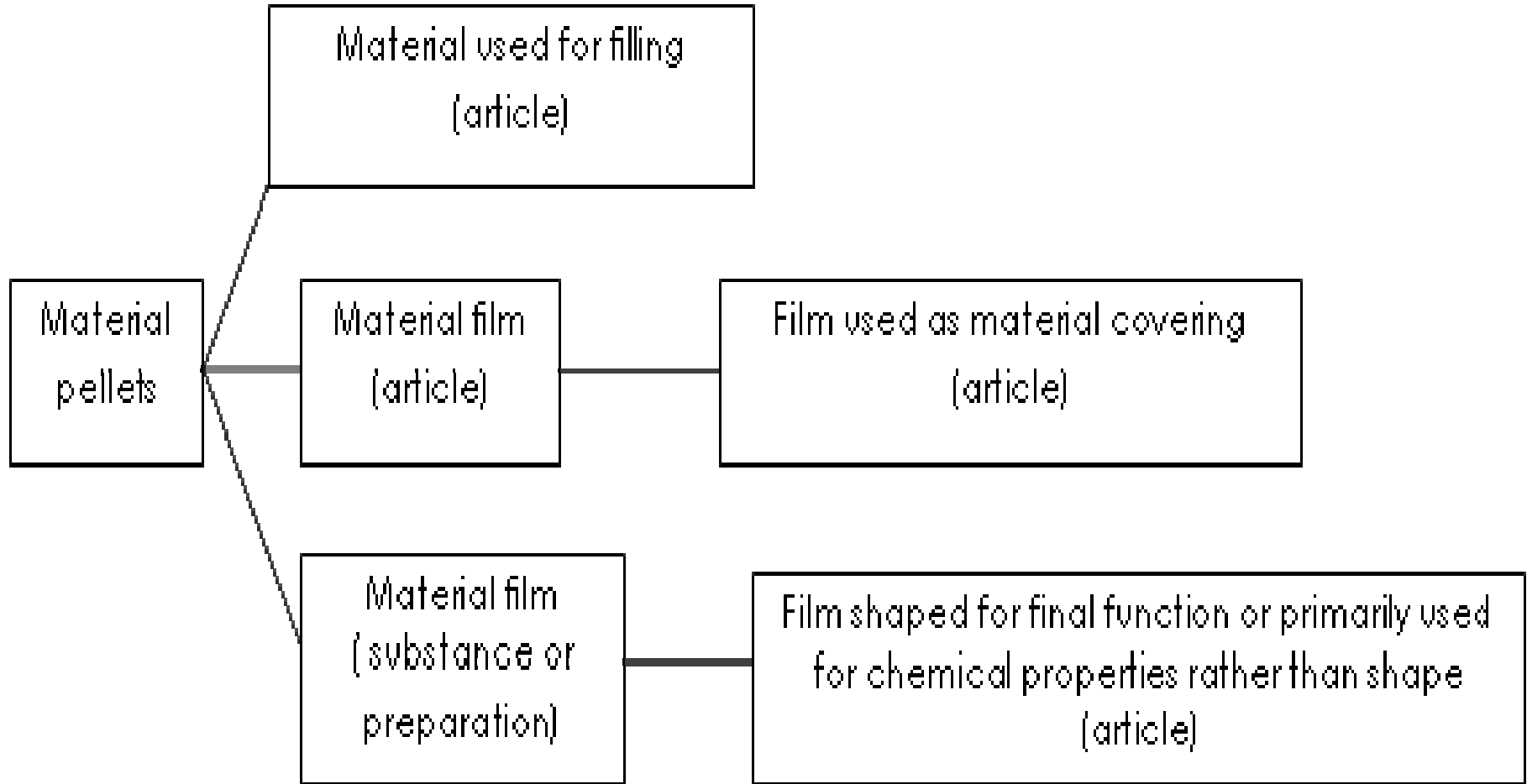
Substance

Substance in
preparation

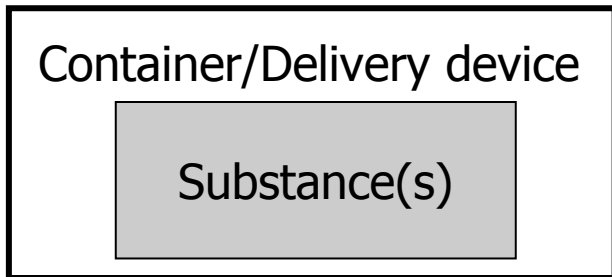
Substance intended to be
released from an article

*Substance registration for each substance ≥ 1 tpy
(except substance intended to be released from an
article if 'use' already registered)*

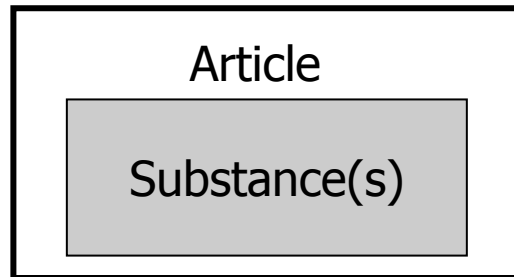
Substance, Preparation or Article?



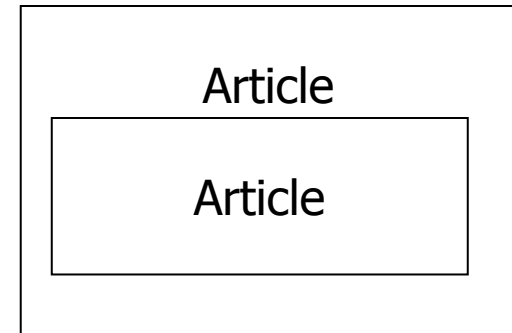
Article or Preparation?



Manage separately
substance(s)
subject to
registration as if
substance or
preparation



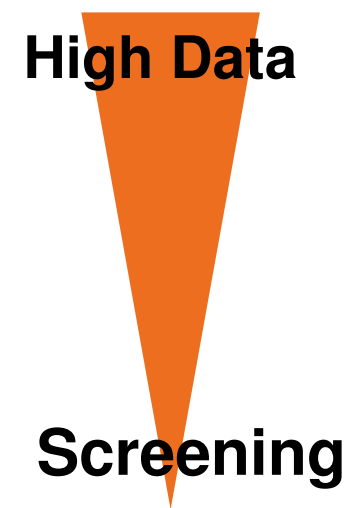
Manage as
article
substance(s)
subject to
registration if
intended release
(unless already
registered)



Manage as
two articles

Registration

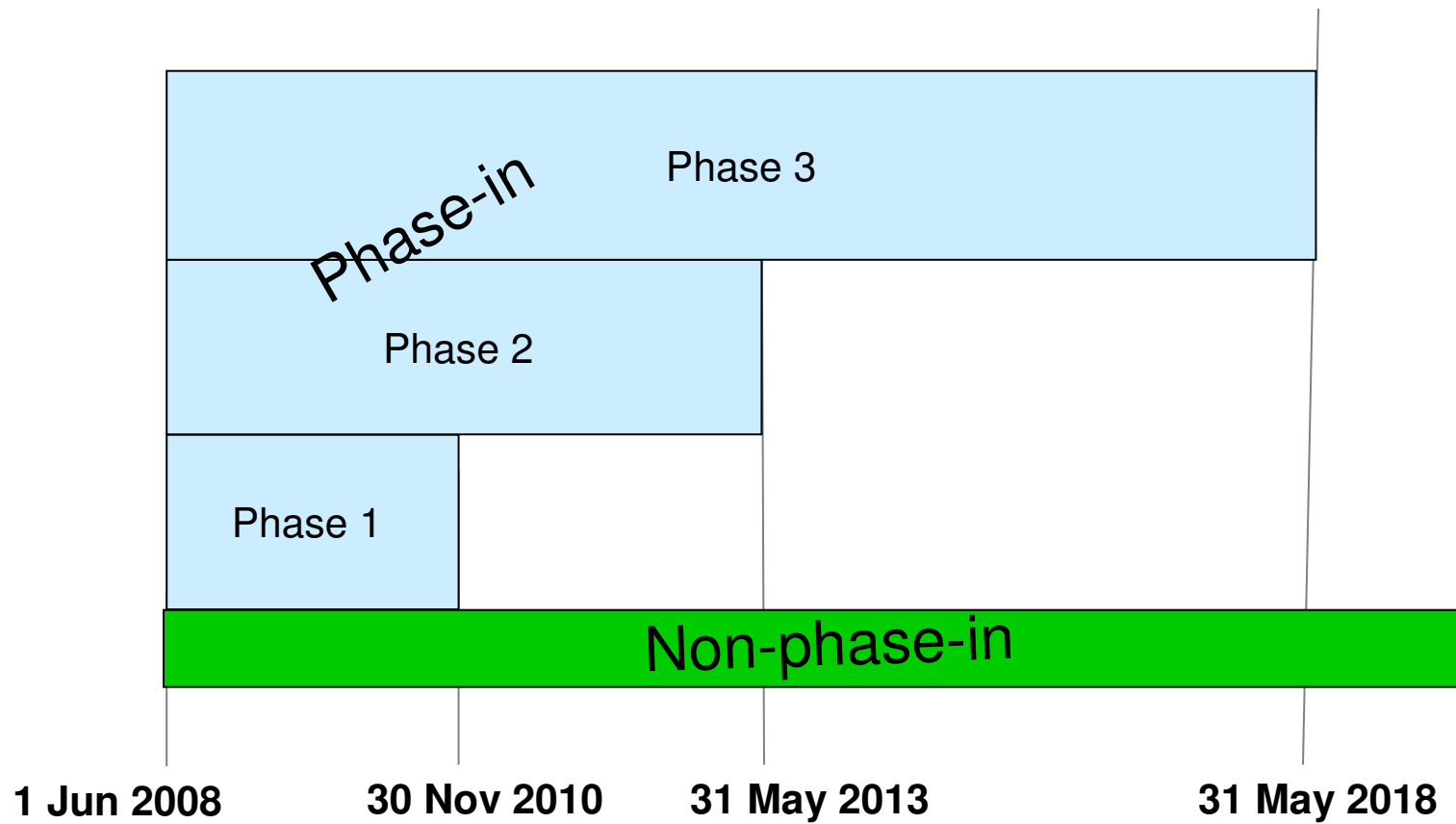
Tonnage of substance tonnes per year (per manufacturer or importer)	Registration Deadline 'phase-in' substances
<p>≥ 1,000 tpy R50/53* ≥ 100 tpy CMR** ≥ 1 tpy</p>	<p>Phase 1 30 November 2010</p>
<p>100 - 1,000 tpy</p>	<p>Phase 2 31 May 2013</p>
<p>10 - 100 tpy</p>	<p>Phase 3 31 May 2018</p>
<p>1 - 10 tpy</p>	
<p><1 tpy</p>	<p>Exempt from registration but not from all of REACH</p>



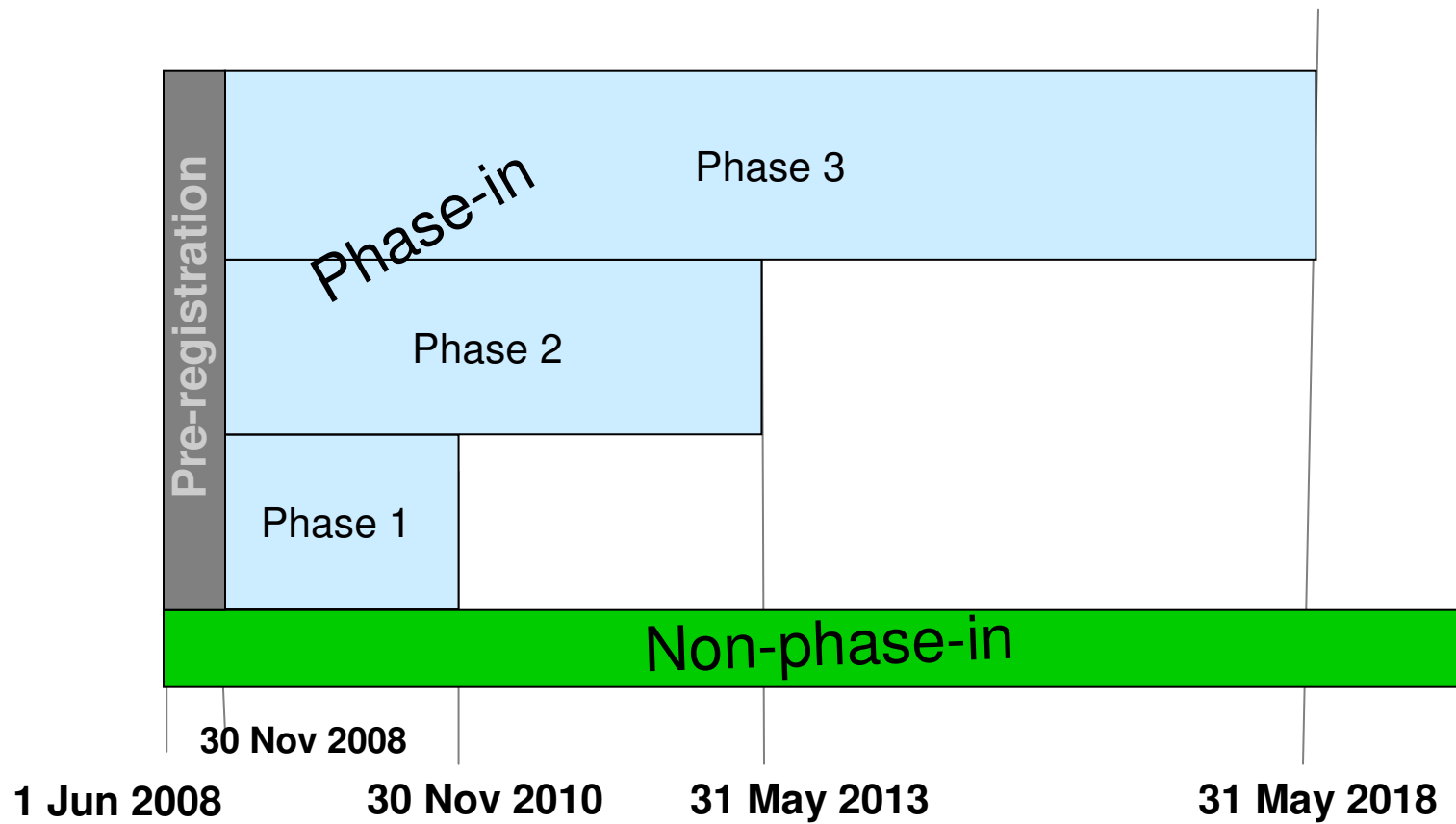
*certain substances identified as 'dangerous to the environment'

**carcinogenic, mutagenic and reprotoxic substances

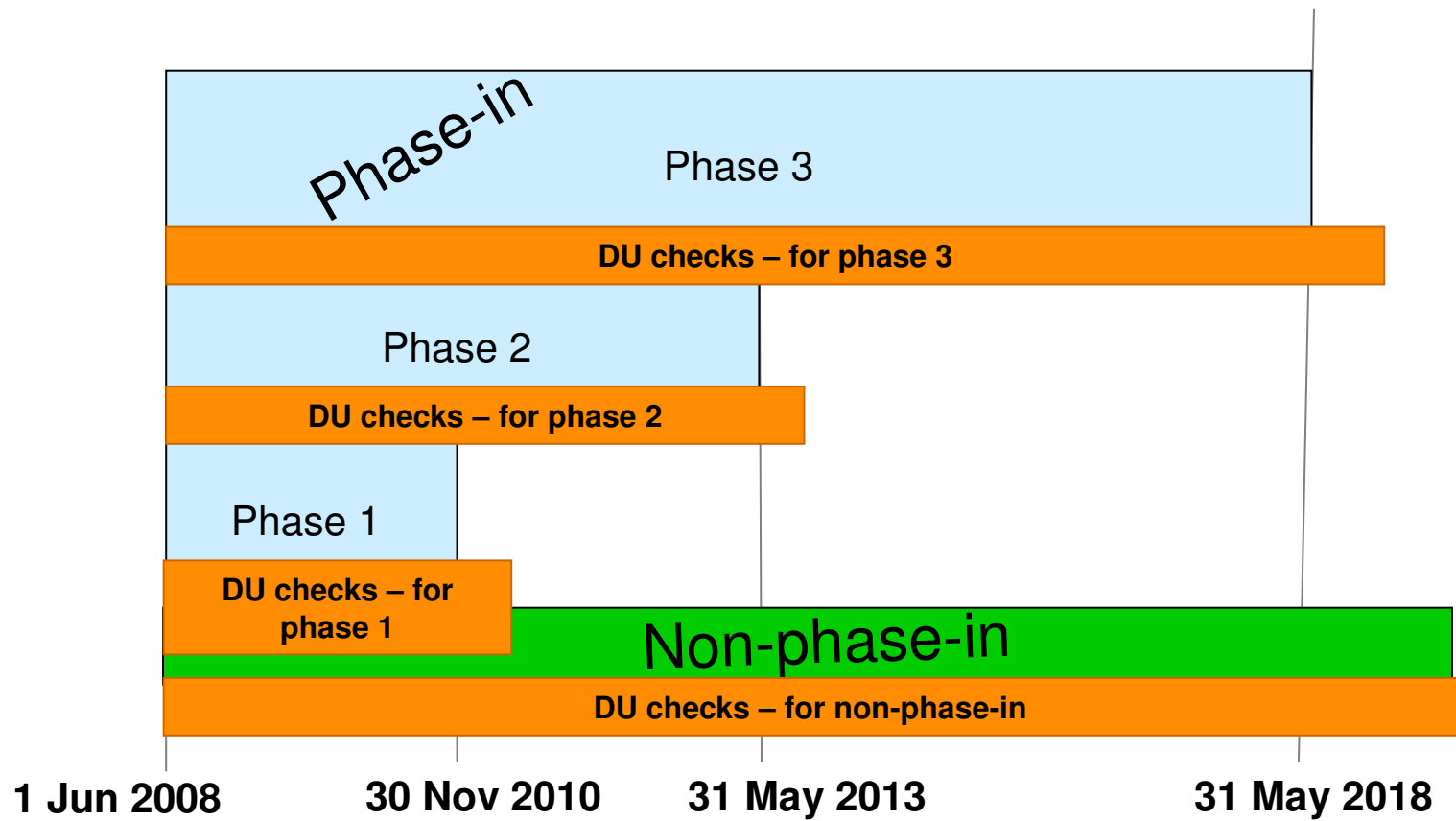
Registration Deadlines



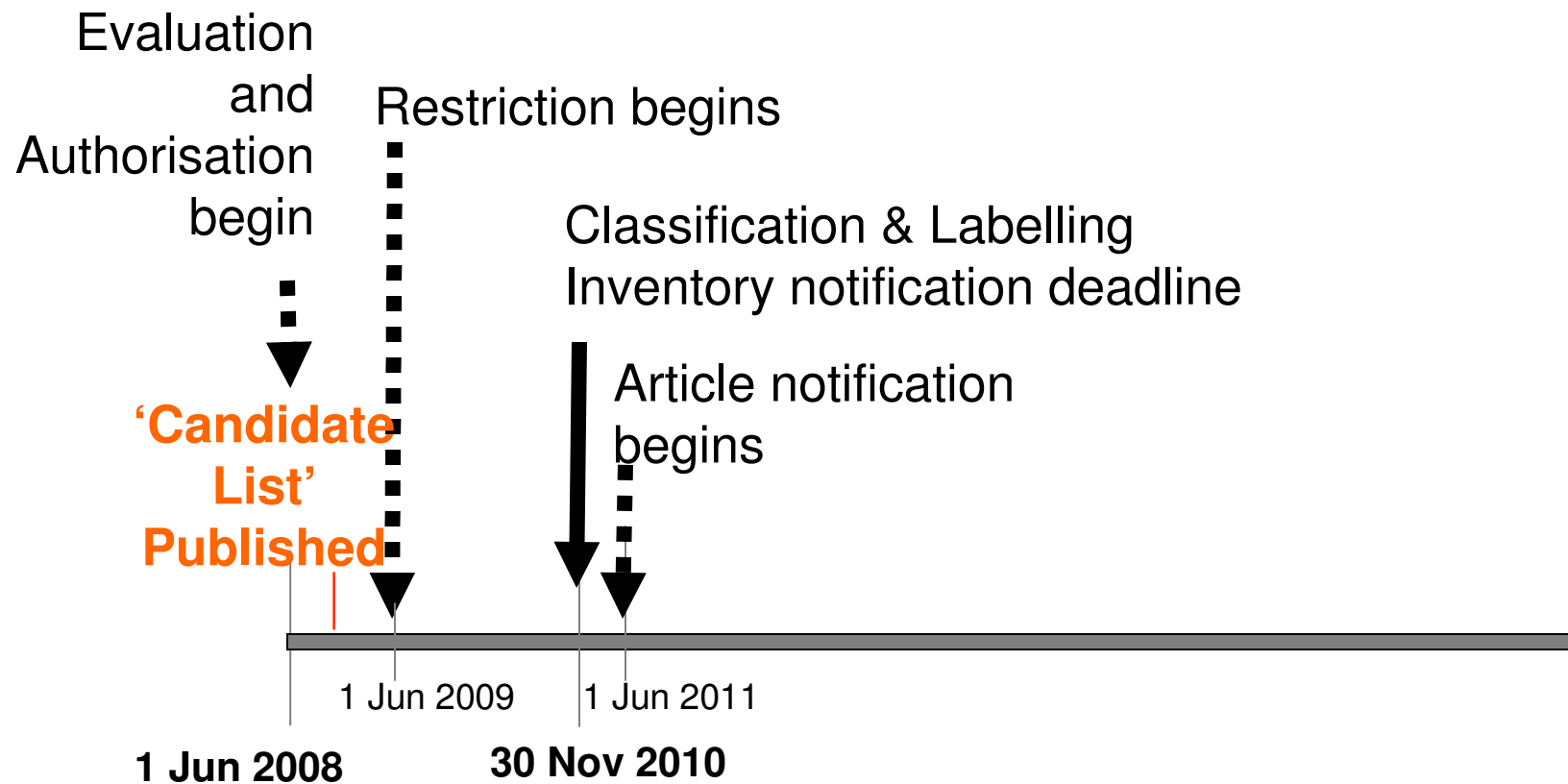
Registration Deadlines



Downstream User Timelines



Additional Timelines



Polymer requirements

First Legal Challenge:

**Polymers – as defined under REACH –
are (currently) exempt from registration**

- (a) >50% weight majority of 3+1 monomers or other reactants covalently bound;
and
- (b) <50% weight majority of molecules of the same molecular weight

However:

**Monomers and other chemically bound substances must
be registered by every manufacturer* and importer
(if above 2% w/w and above 1 tonne)
even if manufacturing occurs outside the EU**

**current debate over role of polymer processors*

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Methods

- Must be done online via REACH-IT portal via http://echa.europa.eu/reachit/portal_en.asp

Contact | Search | Help

ECHA

You are connected as **ljohnson** on behalf of The Chemical Company - [Preferences](#) - [Logout](#)

Home

You have 0 unread message(s) in your message box

Company	
Pre-registration	
Pre-SIEF	
Phase-in Information	
Registration / notification	View registration / notification
Joint submission	Submit registration / notification
Message Box	
User account management	Registration / notification utilities
Utilities	

Functional menu

Page Content

HSE, 2008

<http://www.hse.gov.uk/reach/events/preregistration.pdf>

Registration Costs

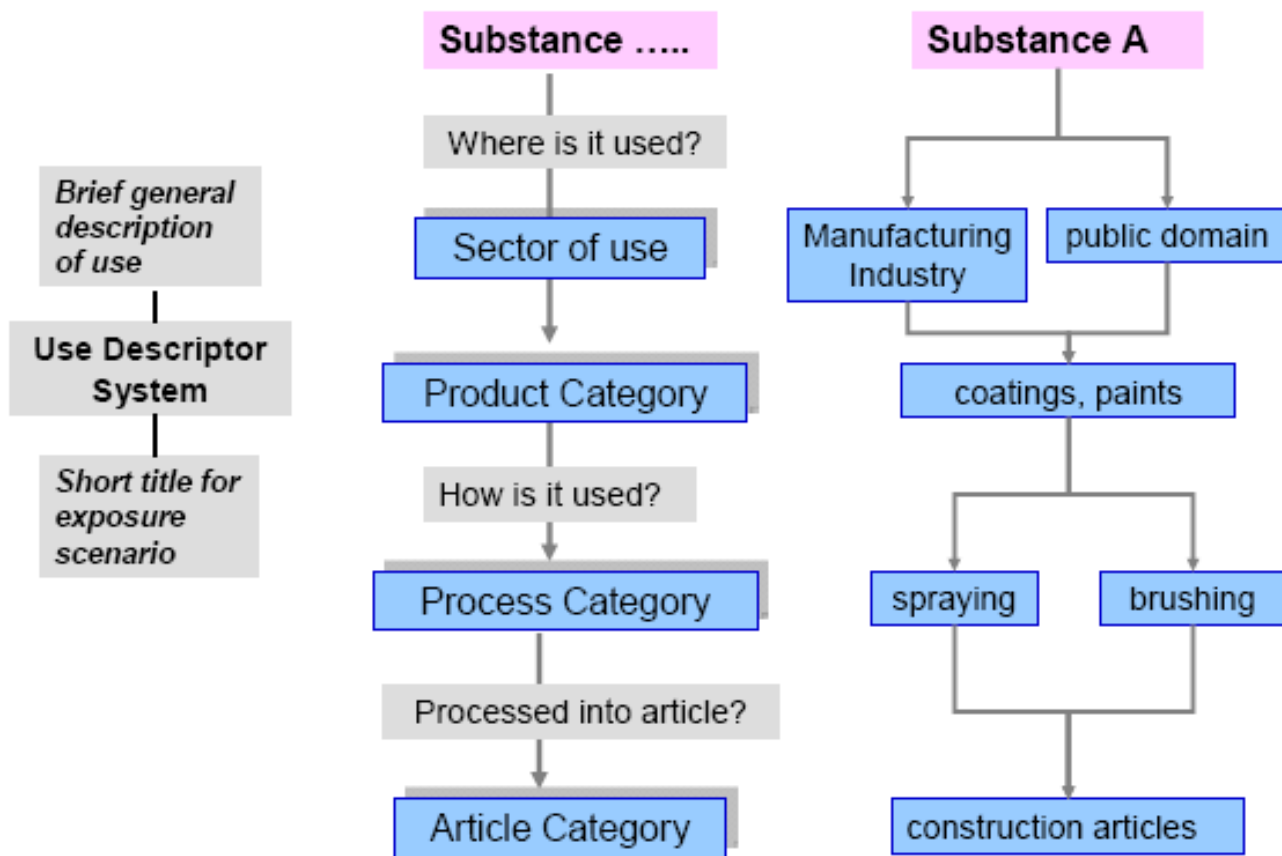
- Anticipated costs:
 - Tremendous uncertainty but on average when accounting for 'available data' registration costs for a typical substances have been estimated by KPMG (2005):

Tonnage	Cost (Euro)
1-10 tpy	15 000
10-100 tpy	160 000
100-1000 tpy	280 000
>1000 tpy	320 000

- Actual costs:
 - Will be divided amongst registrants
 - May be up to 10x higher, esp. if company is not a data holder
 - Must account for administration and include fees

Use Description

(RIP 3.2/3.3, ECHA, 2008)

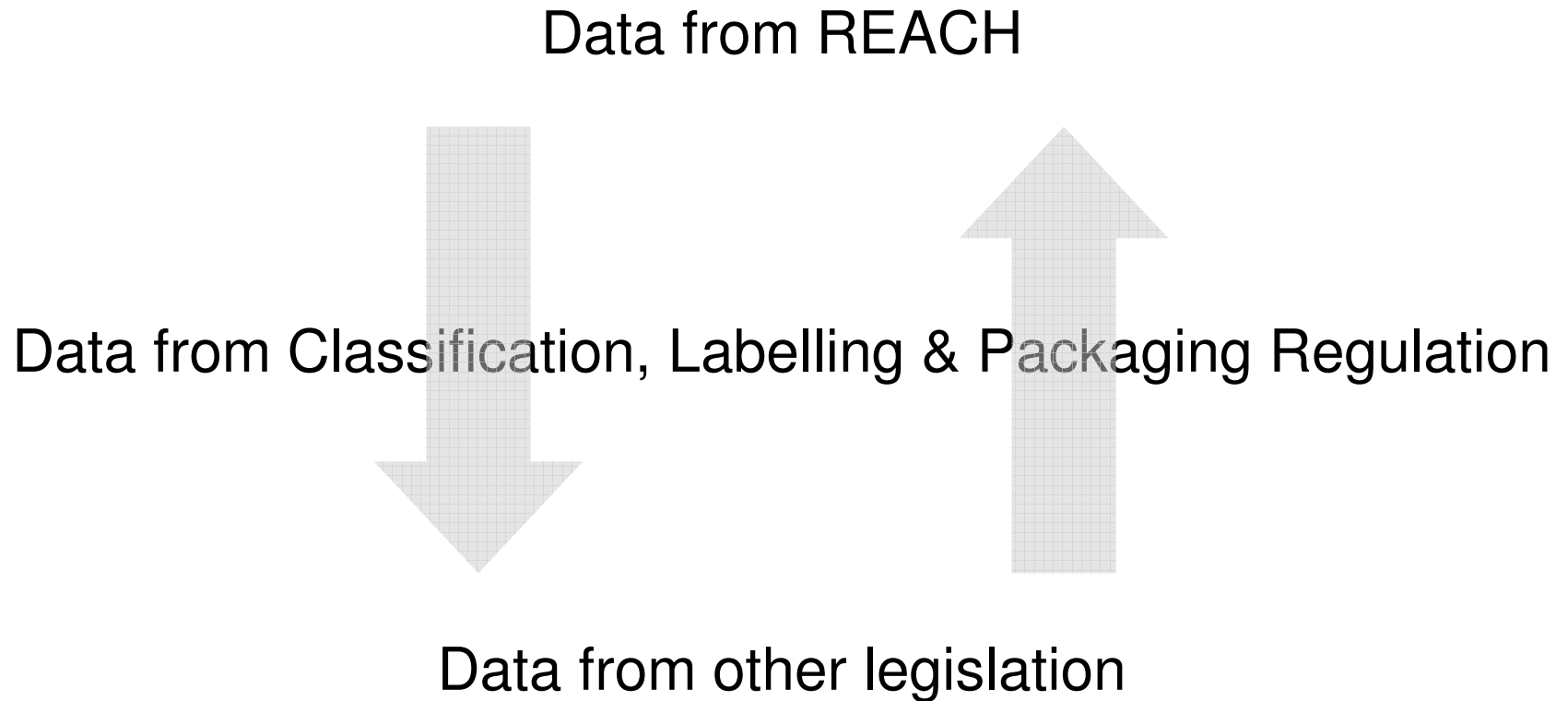


Use & Exposure Categories

Potential link to Exposure-Based Waiving – Annex XI

Exposure			Industrial Use	Professional Use	Consumer Use
Human	Oral	Short Term			
		Long Term/Repeat			
	Dermal	Short Term			
		Long Term/Repeat			
	Inhalation	Short Term			
		Long Term/Repeat			
Environment	Water	Single Instance			
		Long Term			
	Air	Single Instance			
		Long Term			
	Soil/Solid Waste	Single Instance			
		Long Term			

Managing REACH



References

ECHA references sourced from website:

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

Other references from document library in folders available via:

Consumer Products Safety & Quality (formerly European Chemicals Bureau)

Institute of Health and Consumer Protection

Joint Research Centre

<http://ecb.jrc.ec.europa.eu/>