



Twinning Light

MT04-IB-OT-03

REACH – New Chemicals Management



Phase 1
28th March 2007
Helmut Witzani

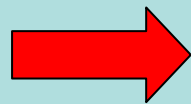


Twinning Light

MT04-IB-OT-03

Legal Framework at present

- **67/548/EEC** **Dangerous Substances Directive**
- **76/769/EEC** **Limitations Directive**
- **1999/45/EC** **Preparations Directive**
- **(EEC) 793/93** **Existing Substances Regulation**
- *(EC) 2037/2000* *Ozone Depleting Substances Regulation*
- *(EC) 304/2003* *Export/Import-Regulation / PIC Reg.*
- *(EC) 850/2004* *POPs Regulation*
- *98/8/EC* *Biocides Directive*
- *(EC) 648/2004* *Detergents Regulation*



- Notification of new substances
- Testing methods, GLP
- Classification & Labelling (C&L), SDS
- Risk assessment / risk management
- Restrictions of marketing and use





Why REACH?



Twinning Light

MT04-IB-OT-03

- New substances
 - Well running system with high efforts but limited effects on protection of human health and environment
- Existing substances
 - Slow progress
 - Lack of data





Existing Substances



Twinning Light

MT04-IB-OT-03

- Obvious need for action
- Requirements acc. TGD vs. high number of relevant substances
- Complex procedure (MS, TM, CSTE, Article 15, recommendation as result)
- No real updating (Article 7 not sufficient)





New Substances



Twinning Light

MT04-IB-OT-03

- High workload for industry and authorities
- Lack of innovation due to low flexibility
- Main problematic issues:
 - Polymers
 - R & D
 - Intermediates





Goals



Twinning Light

MT04-IB-OT-03

- Unique system for new and existing substances
- Risk management (instead of almost scientific assessment of risks ending in itself)
- Acceleration of the process
- Shift of responsibility to industry
- Effective measures for substances of major concern (authorisation)





History



Twinning Light

MT04-IB-OT-03

- Criticism from MSs, IND, NGOs
- EC study "4 instruments":
 - DSD, Preps-D, Limitations-D, ESR
- EU Commission: white paper 2001
- First draft, internet consultation
- EU Commission: proposal for legislation in 2003
- EU Parliament: first reading of legislation in 2005
- EU Council: political agreement Dec. 2005
- EU Commission: Common Position June 2006
- EU Parliament: second reading in 2006
- REACH will enter into force on 01.06.2007



- **Registration** (substances \geq 1 tonne)
- **Evaluation** (by the Member States)
- **Authorisation** (substances of very high concern) &
- **Restriction** (the safety net) of
- **Chemicals and the Agency to manage the system**



Subject (Article 1)



Twinning Light

MT04-IB-OT-03

Provisions on substances

- Manufacture
- Import
- Placing on market
- Use

on their own, in preparations or in articles





Scope (Article 2)



Twinning Light

MT04-IB-OT-03

- REACH does not cover:
 - Radioactive substances
 - Substances under customs supervision
 - Non-isolated intermediates
- Supports legislation on:
 - Occupational safety and health
 - Transport of dangerous goods





Registration

≥ 1 t/ year

Evaluation

≥ 100 t/year
 +substances
 of concern
 (<100t)

Authorisation

Annex XIV

CMR cat. 1&2
 (67/548/EEC)

PBTs/vPvBs
 (Annex XIII)

Endocrine
 disruptors

...

Restrictions

Annex XVII

POPs

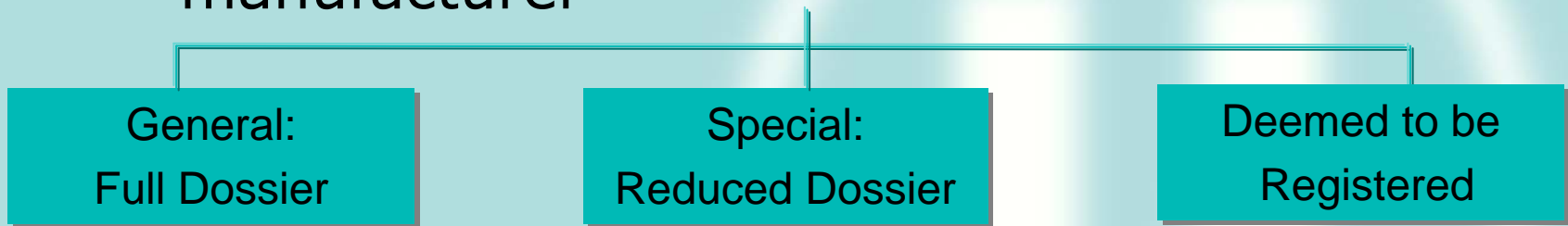
76/769/EEC

->Annex XVII



Registration

- Obligations to register: manufacturer, importer, EU representative of non-EU manufacturer



- ≥ 1 t/yr per M/I
- Monomers
- Substances in articles

- Isolated intermediates
- On-site (Art. 17)
- Transported (Art. 18)

- Biocides
- Pesticides
- Notified substances (67/548/EEC)



Substances in Articles (Article 7)



Twinning Light

MT04-IB-OT-03

Registration

- Meet the criteria for classification as dangerous
- > 1 t/yr per article type per M/I
- Not registered further up the supply chain

- Intended to be released



Obligation to register

- Likely to be released - but not intended
- Quantity released may adversely affect human health or the environment



Obligation to notify the Agency



Agency may require registration





Exemptions



Twinning Light

MT04-IB-OT-03

Registration

- Uses covered by other legislations
 - Medicinal products, food additives, flavourings in foodstuff, feeding stuff additives, animal nutrition, cosmetic products
- Exempted from Registration
 - Substances < 1 t / year
 - Annex IV (well known substances)
 - Annex V (radioactive substances, by-products etc.)
 - Polymers (subject to review)
 - Non-registered substances < 2% in polymers
 - PPORD substances (time limited)





PPORD (Article 9)



Twinning Light

MT04-IB-OT-03

Registration

- Product and Process Orientated Research and Development
 - 5-year exemption (begins at receipt of notification)
 - Agency may impose conditions
 - Extension up to 5 years
 - Extension up to 10 years (exclusively for development of medicinal products for human or veterinary use)





Registration

- Technical Dossier (Art. 10, 12 and Annexes VI to XI) > 1 t /year
 - Identity of substance & manufacturer or importer
 - Quantity
 - Information on identified uses
 - Proposed C&L
 - Guidance on safe use
 - Information on properties (phys-chem., tox., ecotox.)
 - Testing proposal if further testing required



Registration

- Information requirements

	Annex VII	Annex VIII	Annex IX	Annex X	CSR
≥ 1 t/yr	X				
≥ 10 t/yr	X	X			X
≥ 100 t/yr	X	X	X		X
≥ 1000 t/yr	X	X	X	X	X



Chemical Safety Report (CSR)



Twinning Light

MT04-IB-OT-03

Registration

- Includes **Chemical Safety Assessment (CSA)**
 - Hazard assessment:
 - Phys.-Chem.
 - Human Health (->DNELs)
 - Environment (->PNECs)
 - PBT and vPvB assessment
 - Exposure assessment
 - Risk characterisation
 - > RMM development for dangerous substances or PBT/vPvB
- > Lower limit values for substances in preparations





Data sharing Non-phase in substances



Twinning Light

MT04-IB-OT-03

Registration

Registration of same substance?

no

Vertebrate animal **tests allowed**

yes

Registration >10 years ago

no

Agency informs potential registrant about

- available animal tests
- other tests that previous registrants are willing to share

Agency enables contact with previous or other potential registrants

yes

Agency provides

- summary or
- robust study summary

Vertebrate animals
tests shall **not** be
repeated!





Data sharing Phase-in substances



Twinning Light

MT04-IB-OT-03

Registration

Pre-registration required for all substances

- Aim: identification of other potential registrants
- deadline for the registration/tonnage band
1.6.2008-1.12.2008
- **SIEF** (Substance Information Exchange Forum)
 - Sharing of available information
 - Who will perform new test on behalf of other SIEF participants?
 - Formation of Consortia (sharing of costs)





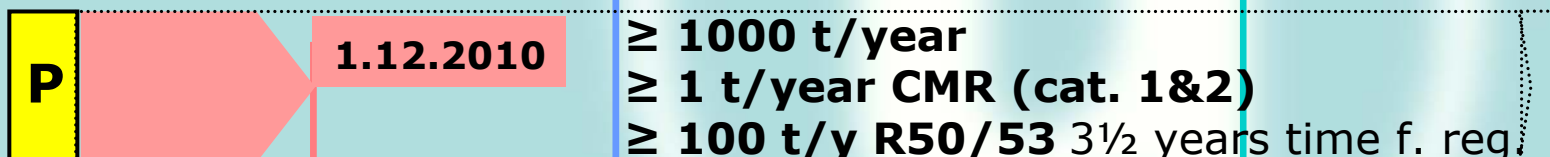
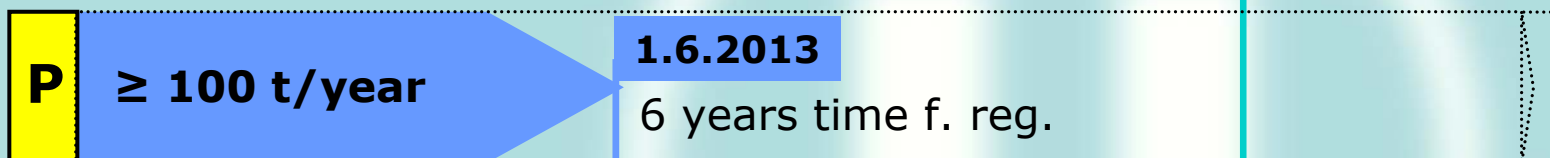
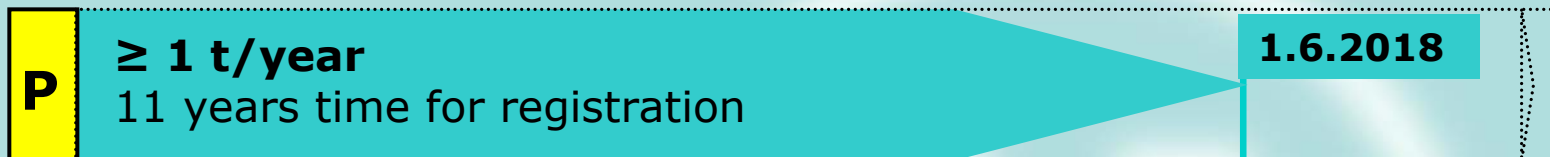
Time table



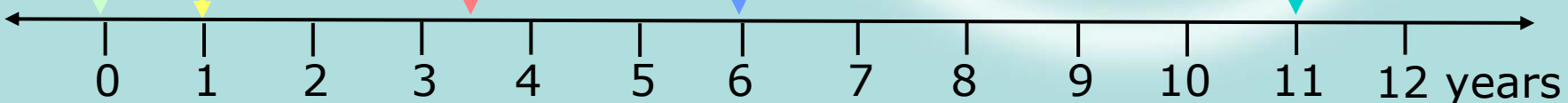
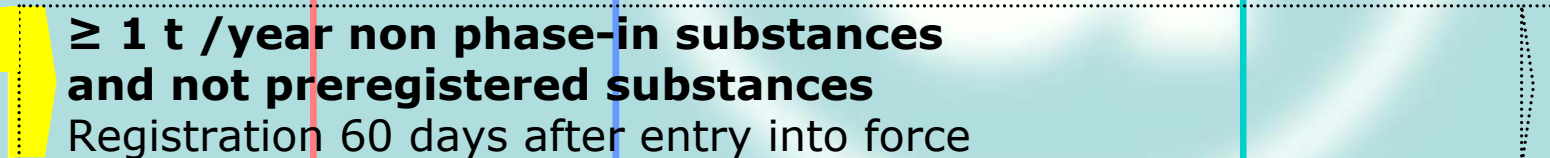
Twinning Light

MT04-IB-OT-03

1.6.2007



1.6.2008





Downstream Users (DU) (Article 37-39)



Twinning Light

MT04-IB-OT-03

- Uses a substance either on its own or in a preparation in the course of his industrial or professional activities
- Is one of the actors in the supply chain
- Is not manufacturer, importer, distributor or consumer



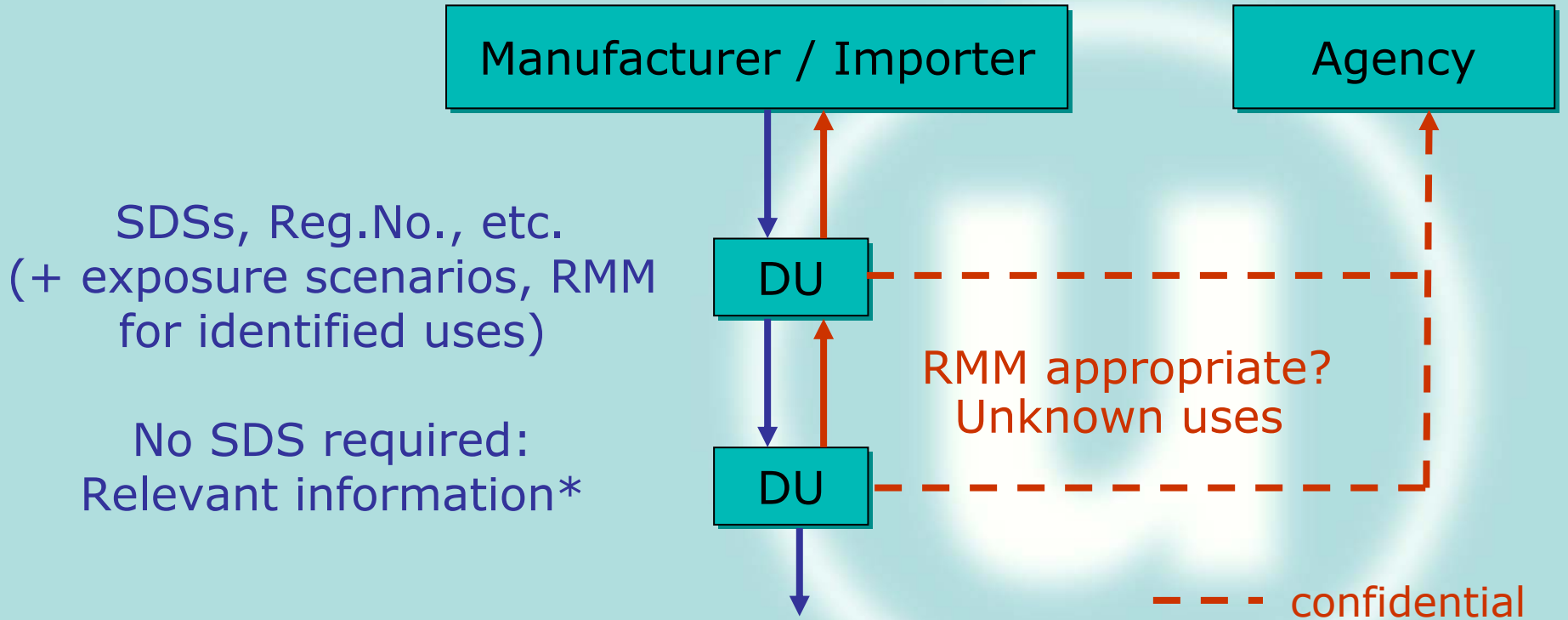


Information through the Supply Chain



Twinning Light

MT04-IB-OT-03



*Relevant information: Reg.No., details on authorisation/restriction, relevant information for RRM





Safety Data Sheets (Article 31)



Twinning Light

MT04-IB-OT-03

- Directive 91/155/EEC incorporated in REACH
 - Same scope as before + communicator
 - Main tool for communicating information downstream
- > Duties to pass relevant information down the supply chain - even if no SDS is required

Content: standard information: intrinsic hazards of the chemical
Annexes: details on identified uses and recommended RMM





Evaluation



Twinning Light

MT04-IB-OT-03

Evaluation

≥ 100 t/year

+

substances
of concern
(<100 t)

Mandatory evaluation ≥ 100 tpa
optional evaluation <100 tpa substances of concern

- Dossier evaluation:
 - > examine proposals for testing
 - > compliance check for registration
- Substance evaluation:
 - > Prioritising of substances
 - > Decision making by consultation of MS CAs
 - > Identification of substances of concern
authorisation
restriction





Dossier Evaluation



Twinning Light

MT04-IB-OT-03

- Competent Authority of Member State:
 - Where manufacture takes place or importer is established
- Consortia:
 - CA of Member States of the manufacturer or importer who submits information on behalf of others





Dossier Evaluation



Twinning Light

MT04-IB-OT-03

prevent animal tests + ensure high quality of tests

Article 40

Examination of testing proposals

⇒ request to carry out the tests

ensure high quality of dossiers submitted

Article 41

Compliance check, esp. waiving statements

⇒ require information needed for compliance

Registrants submit information required
Check of information submitted ⇒ conclusion





Substance Evaluation



Twinning Light

MT04-IB-OT-03

clarify the suspicion of risks to human health or the environment of a substance

Article 46
Request for further information

Registrants submit information required
Check of information submitted ⇒ conclusion





Twinning Light

MT04-IB-OT-03



Authorisation

Authorisation Annex XIV

CMR cat. 1&2
(67/548/EEC)

PBTs/vPvBs
(Annex XII)

Endocrine
disruptors

...

Substances included in Annex XIV need to be authorised for use and placing on the market

Authorisation granted when

- risk (HH, ENV) from use is adequately controlled or
- socio economic benefits outweigh the risks to HH/ENV and no suitable alternative exists





Authorisation



Twinning Light

MT04-IB-OT-03

Substances potentially subject
to authorisation
Art. 57

Stockholm POPs
CMRs (1+2) for use by
consumers

Substances that may be
included in Annex XIV
CMRs (1+2)
Identified substances

Substances to be identified:
•PBT, vPvB (Annex XIII criteria)
•Equivalent serious and
irreversible effects
e.g. vPvB, PBT (non Annex XIII)
•Endocrine disruptors

**Restriction
process**

Establishment of
Annex XIV

Identification process





Authorisation



Twinning Light

MT04-IB-OT-03

- Information specified in Annex XIV:
 - Identity of substance
 - Identified properties (that lead to authorisation)
 - Transitional arrangements (already on market/used):
 - "Sunset date"
 - Application date
 - Review periods
 - Exemptions



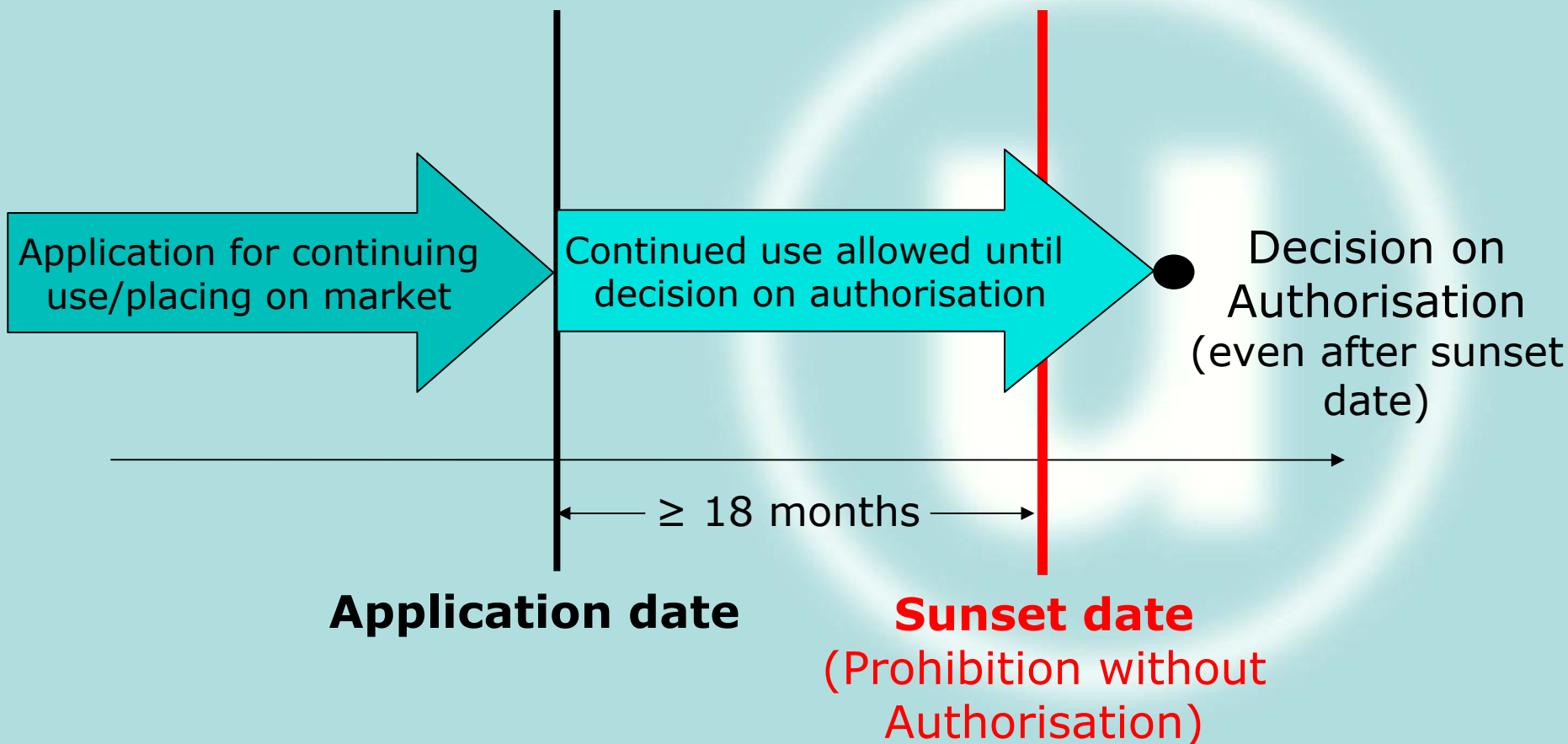


Authorisation



Twinning Light

MT04-IB-OT-03





Twinning Light

MT04-IB-OT-03



Restrictions

Restrictions

Annex XVII

POPs

76/769/EEC

->Annex XVII

- **Safety net**
- RMM **Community-wide**
- Based on risk assessment - different from CSR (-> regional exposure, aggregated volumes, etc)
- Restrictions apply to all M/Is, DUs, distributors

Scope

- Substances on their own, in preparations, in articles
- Regardless of any duty to register and of quantity (unless thresholds specified)
- Exempted: substances used for scientific R&D, PPORD < 1tpa, waste





Restrictions



Twinning Light

MT04-IB-OT-03

Procedure for new restrictions:

- Agency (asked by COM)/ MS prepare dossier
 - -> socio-economic analysis
 - commenting period (public)
- Agency: submit opinions of the risk assess. & socio-economic analysis committees to COM
- COM: Inclusion in Annex XVII

More rapid for consumer use of CMR cat 1&2, POPs

- COM prepares dossier
- Inclusion in Annex XVII





Procedure



Twinning Light

MT04-IB-OT-03

>1 tonne:
M/I gathers information on

- Properties
- Identified uses
- Safe management

Registration

European Chemicals Agency

Evaluation

Most substances:
No further action

No further action

Industry can be asked for more info

No authorisation
use is not considered to be adequately controlled

MS/Agency

Dossier evaluation:

- Of animal testing (mandatory)
- Of compliance (optional)

Substance evaluation:

- Suspicion of risks (optional)

Substances needed to be regulated further

It has very hazardous properties

It poses unacceptable risks

Authorisation
is granted by COM

Risk assessment is reviewed

Industry says will be adequately controlled

No authorisation
Benefits too small compared to risks
Suitable substitutes available

Socio-economic benefits and possibility for substitution are weighed against risk

Industry: will not be adequately controlled

Authorisation*
CMR, PBT, vPvB, or equivalent serious and irreversible effect and should not be used without authorisation

Restrictions* by COM
Based on MS dossiers, COM can decide on RMM, ban certain uses/substances altogether



C & L Inventory (Article 114)



Twinning Light

MT04-IB-OT-03

M/I: submission of C&L required 3 years after entry into force

- All dangerous substances
- Substances subject to registration (even if not classified)

independent of quantity

-> C&L inventory – available to the public

Annex I of Dir. 67/548 under REACH

-> only for **CMRs** (cat. 1, 2, 3) and **respiratory sensitisers**

Harmonisation of all other classifications -> task of industry





Relationship to Workplace Legislation



Twinning Light

MT04-IB-OT-03

- SDS and CSR

-> key tool for development of RA under Dir. 98/24/EC
(protection of health and safety of workers at work)

-> under REACH more information available for workplace
RA (exposure scenarios communicated by SDS!)





Enforcement



Twinning Light

MT04-IB-OT-03

- Control activities under the responsibility of the MSs
- Provisions on penalties shall be laid down by MSs and measures shall be taken in order to ensure the implementation of the legal provisions
- Report on results of controls submitted by the MSs to the Agency
- The “**Forum**”: A platform for enforcement of chemicals legislation at the Agency among other committees





Enforcement and Monitoring



Twinning Light

MT04-IB-OT-03

Member States:

- Compliance check required covering manufacturers, importers, downstream users and distributors at all stages
 - system of official controls and other activities
- Notification of national sanctions for non-compliance
- Introduction of sanctions for non-compliance (fines)
- Yearly reporting of national enforcement activities

Commission:

- Establishes the Forum at the Agency (to serve a network of contact points)





Documents on REACH



Twinning Light

MT04-IB-OT-03

- DG environment:
<http://www.europa.eu.int/comm/environment/chemicals/reach.htm>
- DG enterprise:
http://ec.europa.eu/enterprise/reach/index_en.htm
- ECB:
<http://ecb.jrc.it/REACH/>
- Process description:
http://ecb.jrc.it/DOCUMENTS/REACH/REACH_PROPOSAL/REACH_process_descriptions_15-06-2004.pdf
- Umweltbundesamt information on web:
<http://www.umweltbundesamt.at/en/reach/>

