



KNCV/NVT/RIVM | 1 December 2006

REACH as a challenge

for politicians, scientists and stakeholders

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rivm

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- Background
- Overview of 'players'
- Overview of 'rules'
- Challenges
 - (all throughout)
- Conclusions

BACKGROUND

Background (1)



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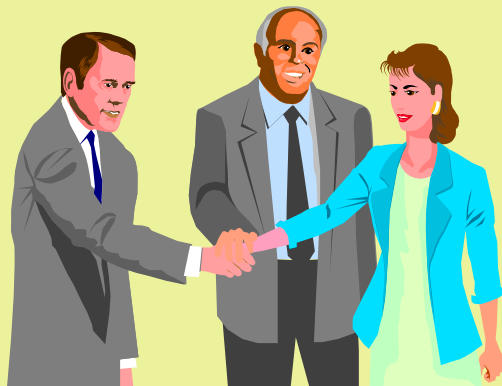
KNCV/NVT/RIVM symposium

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Background (2)

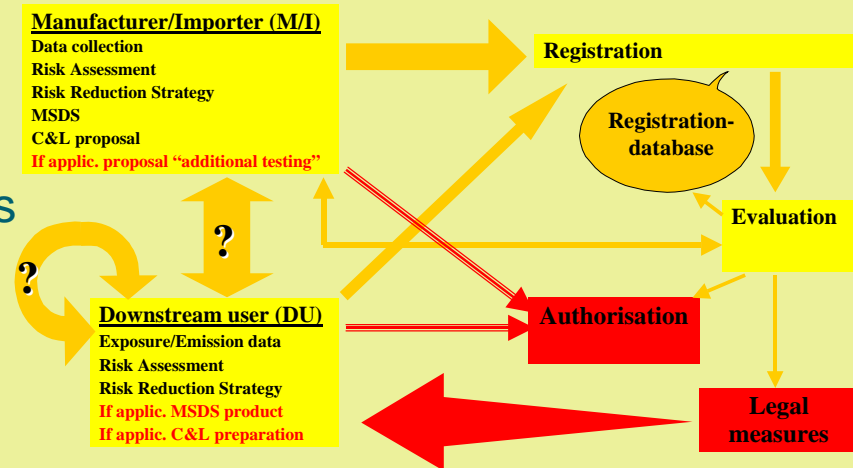
Negotiations

- Before and after proposal of October 2003
- Still changes possible
- 13-12-2005: political agreement?
- From then on: European Parliament and final agreements



Content of REACH

- A whole lot...
- Very complex...



Background (3): Some starting points

Different chemical policies for:

- Existing Substances (793/93)
 - 100,106 substances;
 - 99% of market volume;
 - Risk assessments for \pm 140;
 - Focus on > 1,000 tpa
- New Substances (67/548)
 - ca. 3,000 substances;
 - Notification from > 10 kg pa

***⇒ Differences not good
for internal market***

Furthermore

- Many existing substances not risk assessed

***⇒ not good for
man and the environment***

- Call for reducing animal tests

Background (4): Objectives of REACH

- Protecting man and the environment
- Keeping and improving competitiveness internal market
- Prevent fragmentation internal market
- Improving transparency
- Integration international efforts
- Improving alternatives to animal testing
- Harmonise EU obligations with WTO

Background (5): Update

- 2001: White Paper
- June 2003: internet consultation: > 6000 comments
- October 2003: draft REACH proposal for European Parliament and Council
- 2003-2006(?): start negotiations + INTERIM
- December 2005: Council agreement
- 2006: 1st (and 2nd ??) reading Parliament
- 2007: Implementation of REACH (?)

NB REACH will replace > 60 directives and regulations!

Challenges for politicians

Before internet consultancy round

- Get internal (within an country) organisation efficient
- Get objectives clear
 - E.g., NL: do something about Substances of Very High Concern
 - E.g., NL: take care of Small and Medium sized Enterprises



During negotiations

- Stay awake!
- Read hundreds of papers and thousands of e-mails from different lobbyists, the council and colleagues from other member states

Under REACH

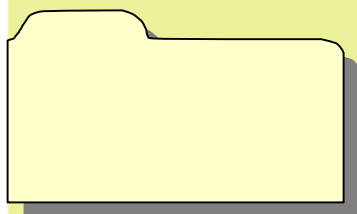
- Keep listen to ‘chemical signals’

REACH.

Registration, Evaluation, Authorisation and restriction of Chemicals

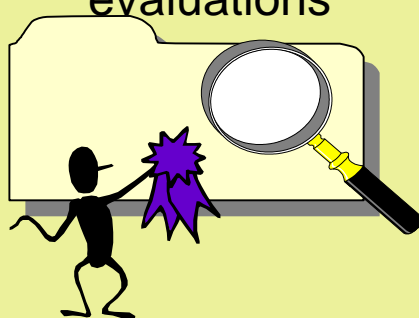
Registration

> 1 tonne/yr



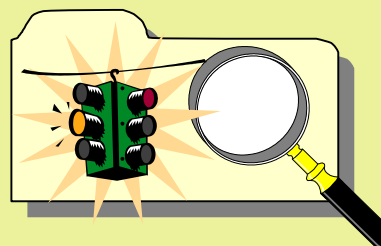
Evaluation

>5% of dossiers
all testing proposals
Some substance
evaluations



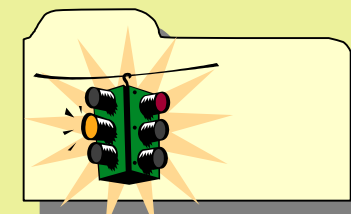
Authorisation

CMR & PBT
and equivalent
concern



Restrictions

Substances of
concern



OVERVIEW OF PLAYERS

Who are the players?

- Manufacturer (M)
- Importer (I)
- Downstream user (DU)

- Agency
- European Commission
- Member States
 - Policy level
 - Execution level

Agency (Helsinki)

- Central role
- Facilitating
- Executive
- Partly paid through fees

- Inspection / Enforcement
- Third parties

OVERVIEW OF RULES

Title I. Aim

- ... to ensure a high level of protection of health and the environment as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation...
- This Regulation is based on ...it is up to manufacturers, importers and downstream users to ensure that they ... substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle...

Title I. General issues (scope)

All substances

- Phase-in substances
- 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
- Substances subject to customary inspection
- Non-isolated intermediates
- Carriage of dangerous substances
- Waste
- Defence (up to Member State)

...where taken care of in other legislation...

Title II. Registration

NO DATA, NO MARKET

Article 5

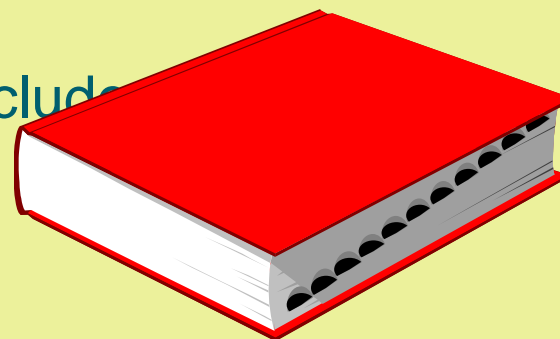
Title II. Registration

Player

- M, I: submit registration (>1 tpa) to Agency
- DU: submit registration for non identified use
- Articles (> 1 tpa):
 - intended to be released
 - Contains Annex XIV substances, > 0.1 % (w/w), except...
- M, I, DU: pay fee!
- Agency: completeness check
- Member states: no role

Title II. Registration

- Includes
 - The substance, the substance in a preparation, or a group of substances
- The Chemical Safety Assessment includes
 - Human health hazard assessment
 - Physicochemical hazard assessment
 - Environmental hazard assessment
 - PBT and vPvB assessment



[If the substance is dangerous or PBT/vPvB, also]

- exposure assessment (including risk reduction measures [to be taken])
- risk characterisation

Title II. Registration

Exceptions

- PPORD (notification still needed)
 - for 5 years
 - plus 5 or 10 (medicines) years
- Pesticides (and co-formulants)
- Active ingredients of biocidal products
- Reduced registration for some (on-site and transported) intermediates

Joint submission of data (OSOR)

- Mandatory sharing of data with opt-out

Title II. Registration

Phase-in substances need to be registered

- CMR cat. 1,2 > 1 tpa < 3 yr
- R50-53 substances > 100 tpa < 3 yr
- EINECS substances > 1000 tpa < 3 yr
- EINECS substances > 100 tpa < 6 yr
- EINECS substances > 1 tpa < 11 yr

Expected number of substances

- ca. 30.000 existing substances (phase-in)
 - ca. 3.000 new substances
- expected number of registrations: 10x, 100x number of substances ???

Pre-registration

- All phase-in substances > 1 tpa, between 12 and 18 months

Titles II & III. Registration & Avoiding unnecessary testing

Objective

- Reducing animal tests (and costs)

How

- Mandatory as well as stimulation of sharing of test results in Substance Information Exchange Forum (SIEF)
- Pre-registration (between 12-18 months)
- Reducing costs (sharing of costs of test results & reduced fees)
- Technical alternatives
 - (Q)SARs !!! NEW !!!
 - in vitro tests !!! NEW !!!
 - existing in vivo data
 - read-across !!! NEW !!!
 - waiving of tests (with motivation)

Challenges for scientists

Before REACH

- Not much...

Implementing REACH

- Providing good guidance for users

Under REACH

- Alternatives
- Exposure scenarios
- Socio-economic analysis
- Please no more PCBs, dioxins, PAH's, Hg, Pb, Zn, but ...

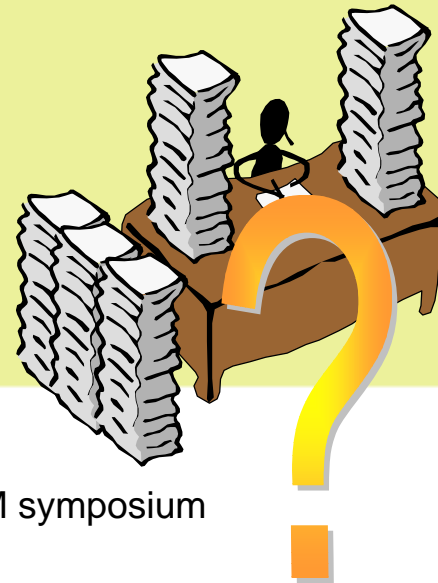
Title VI. Evaluation

Objective

- To verify lack of adverse effects to human health and the environment
- To prevent unnecessary use of animal tests

Two evaluations

- Dossier evaluation, including test proposals (→ Agency)
- Substance evaluation (→ Agency and Member States)



Titles VII & VIII. Authorisation and Restrictions

Objective

- To ensure good functioning of the internal market
- While assuring that risks are properly controlled (substitution)

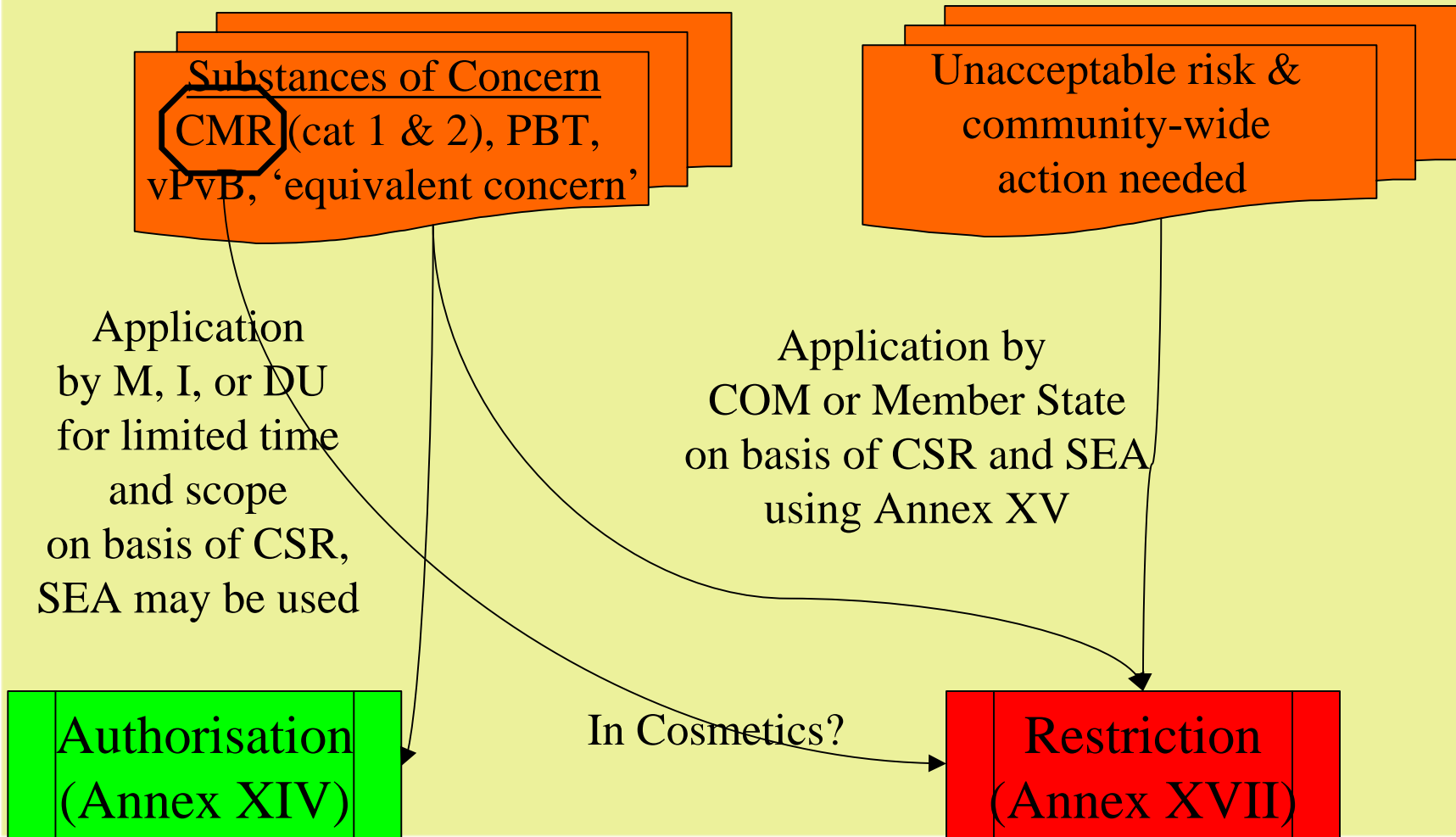
Rules

- No place on the market for any substance on Annex XIV, unless...
 - It is authorised

Annex XIV

- Annex XV dossier to be used to submit proposal
- Must meet criteria in article 54:
 - CMR, PBT, vPvB, or 'equivalent concern'

Titles VII & VIII. Authorisation and Restrictions



Title XI. Classification & Labelling Inventory

Scope

- C&L inventory of dangerous substances and preparations
- At Agency in database
- May include **harmonised C&L**, following 67/548
- May include self-classifications by Industry

Harmonised C&L

- Mainly for
 - CMR cat. 1,2,3
 - respiratory sensitizer
- Also possible for other endpoints (environmental classification, etc.)

**(further)
CHALLENGES**

Challenges for stakeholders

Before REACH

- Via internet consultation
- Via lobbying

Implementing REACH

- Via lobbying and active participation in stakeholder expert groups developing guidance for users

Under REACH

- Provide appropriate information to appropriate REACH elements
 - E.g.: monitoring info to those preparing substance evaluation or restrictions proposal
 - E.g.: new computational techniques to all registrants and to Agency
 - ...

CONCLUSIONS

Conclusions (1)

Players

- Shift in responsibility to enterprises, while authorities keep some
- Agency is extremely important

Replacing animal tests

- For major endpoint (# of test animals) no alternatives (yet)
- Lots of validation and guidance needed
- Sharing of test results (SIEF) does reduce # and \$

Conclusions (2)

Registration: exposure scenarios

- Much more exposure assessors need to be involved

Evaluation

- Requires different mindset
- Resources for evaluation dependent on higher management (within authorities, industry and Commission)

C&L

- Fast, transparent, open to the public
- Question how harmonisation between registrants will proceed
- Role enforcement?

Conclusions (3)

Authorisation & Restriction

- Restrictions
 - Initiative at Agency and Member States
 - Can be triggered by 'society' / stakeholders
- Authorisations
 - Final negotiations?
 - Could become very complex
 - Procedure could take a long time

Conclusions (4)

Challenges

- Politicians
 - Keep listen to 'chemical signals'
- Scientists
 - Any new (scrutinised) information and techniques
 - So, please no more PCBs, etc
- Stakeholders
 - Go to the right REACH 'element'

**THANK
YOU !**