



REACH

An update

Explanatory part of the "screening" - 16-20 January 2006 - Croatia, Turkey

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What is REACH?

One System

- ◆ **Single, coherent system for new and existing chemicals**
- ◆ **Elements:**
 - ❖ Registration of substances ≥ 1 tonne/yr (staggered deadlines)
 - ❖ Information in the supply chain
 - ❖ Evaluation of some substances by Member States
 - ❖ Authorisation only for substances of very high concern
 - ❖ Restrictions - the safety net
 - ❖ Agency to manage system
- ◆ **Focus on priorities:**
 - ❖ high volumes
 - ❖ greatest concern

Recent developments

- ◆ **Parliament 1st Reading: 17 November**
- ◆ **Political agreement at Competitiveness Council: 13 December**

Next steps

Informal discussion between
Council and Parliament with the
support of the Commission

From January till summer 2006

Formal adoption of the
Common Position

May 2006

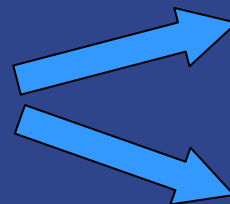
Commission Communication to
the EP on the Common Position

Immediately after the Common
Position

EP Second Reading

Within 3 months from the
reception of the Common Position
(likely September 2006)

Council Decision



Council agrees

or

Conciliation



Commission position

The Commission supports the Political agreement which is consistent with the Lisbon objectives on competitiveness and innovation while achieving a marked improvement in health and environment to the benefit of Europe's citizens.

Main changes introduced - Registration

More targeted approach to the assessment of substances produced/imported in quantities between 1 and 10 tonnes per year.



The new provisions reduce the burden and the costs if compared with the original Commission Proposal in particular for producers of low volume substances which do not meet the criteria for a full data set

Main changes introduced

➔ If a substance is produced in the 1-10t category and it is not prioritised under the criteria set in Annex Ic, only submission of:

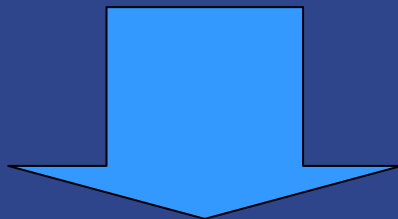
- ❖ Physico-chemical data (no longer required to be GLP conform)
- &
- ❖ Available (eco-)toxicological data
- ❖ But 3 more tests than in COM proposal for prioritised substances

➔ One of two reprotox test no longer needed for 10-100T substances

➔ Exemptions from the obligation to perform DU chemical safety assessment if DU uses the substances or preparation in total quantity of less than 1 tonne per year

Main changes - OSOR

**OSOR (one substance, one registration):
Joint submission of registration data is
strongly encouraged. Sharing of tests is
mandatory but with opt-outs for sharing of
tests.**



Reduction of tests and reduction in testing costs

Main changes - Evaluation

Strengthening of Agency's powers. The Agency will be responsible for dossier evaluation and substance evaluation, the latter will be carried out by the Member States Competent Authorities.



A stronger Agency role will guarantee more homogeneity within the Internal Market while keeping the National Competent Authorities know-how

Main changes - Authorisation

Authorisations may be granted when the risks from the use of a substance can be adequately controlled. However, all demands for authorisation shall be accompanied by an analysis of substitutes. Authorisations shall be subject to a time-limited review whose duration will be determined on a case-by case basis.



The compromise achieved is balanced. By keeping the possibility of granting Authorisations on the basis of ‘adequate control’, it supports industry while providing incentives for substitution and innovation that may improve the environment and health protection level.

Looking forward



The Commission foresees to play a constructive role in the informal discussion between Council and Parliament



The Commission looks forward to an early final agreement that maintains the current balance



Questions ... ?