



REACH – Origin and Purpose

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European Chemicals Agency

Contents

- Origin of **REACH**?
- Purpose:
 - **R**egistration
 - **E**valuation process
 - Brief: **A**uthorisation and restrictions of **CH**emicals

Main four existing legislative instruments for chemicals in the EU

- Directive 67/548: notification of new chemicals, classification and labelling of dangerous chemicals
- Directive 88/379: classification and labelling of dangerous preparations (mixtures)
- Regulation 793/93: evaluation and control of risks of existing substances
- Directive 76/769: Restrictions of marketing and use of certain dangerous substances and preparations

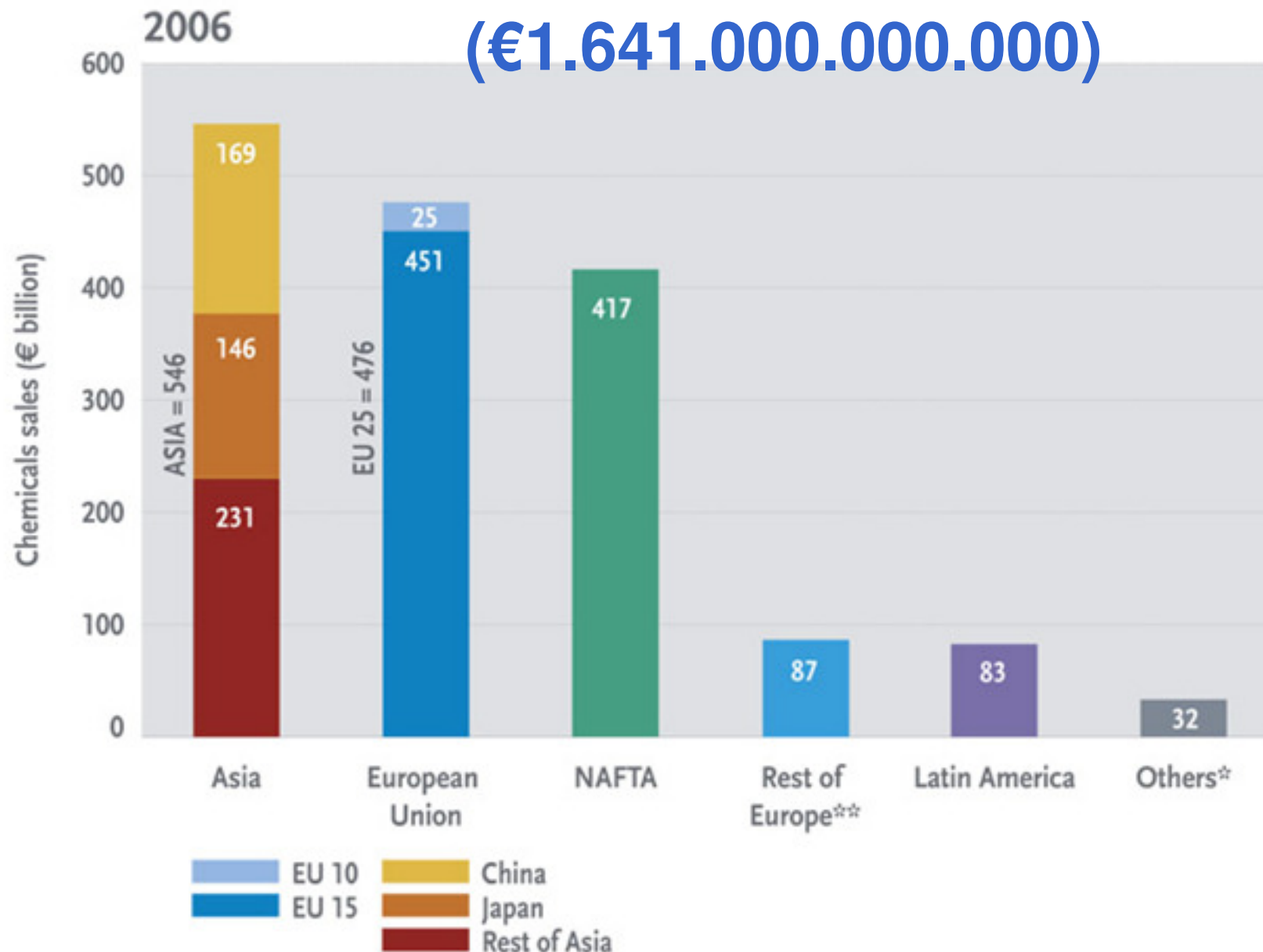
Main Problems

- Data gaps: 86% of HPVCs have less than base set data
- The process takes (far) too much time
- Burden of proof is on public authorities
- Generally Downstream Users stay out of the picture, actual uses of chemicals remain unknown
- The system is inefficient: Industry is faced with a myriad of directives and regulations
- Administrative burden for new, mostly low volume, chemicals prevents innovation

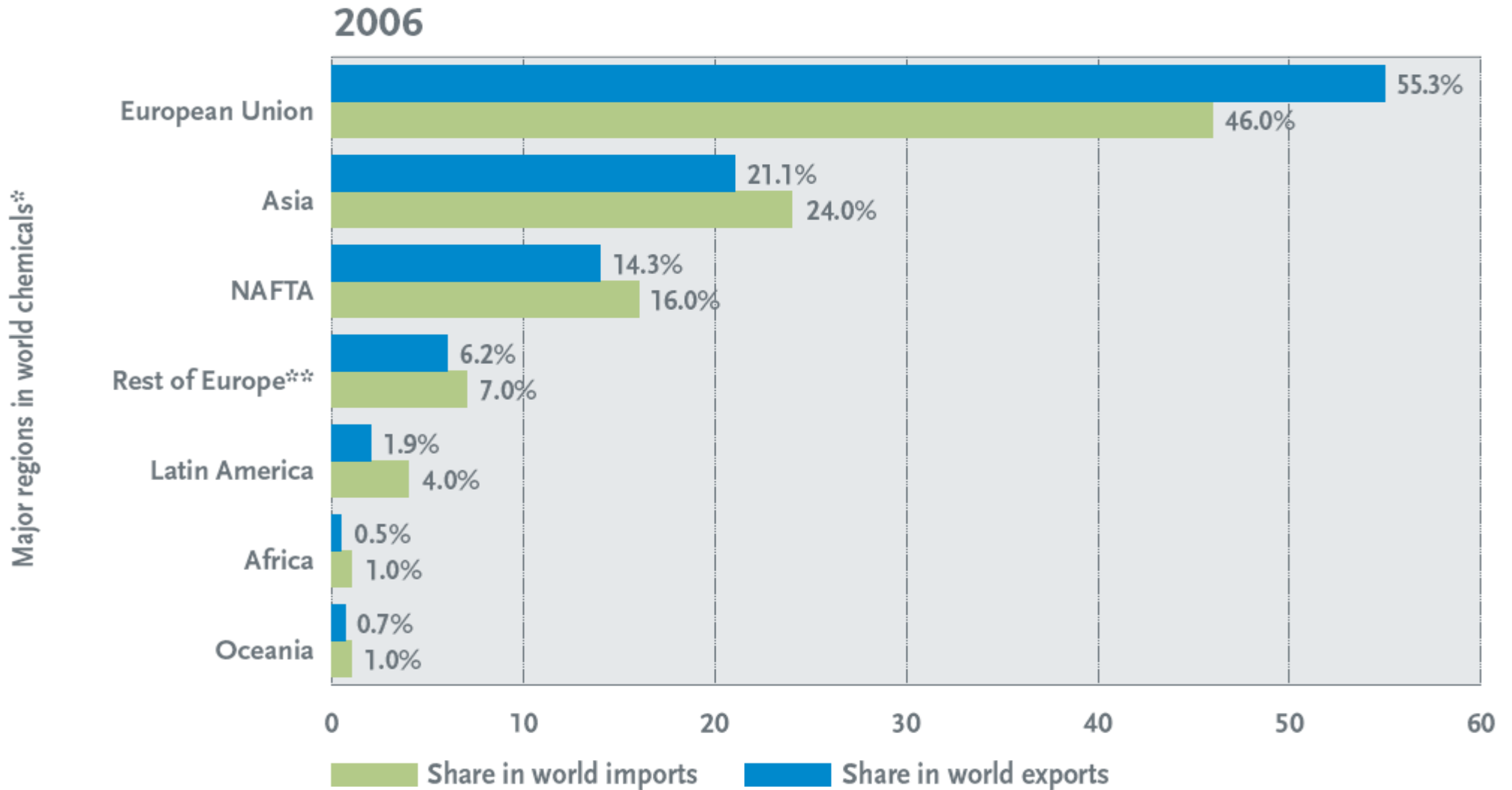
Main Successes of Current Legislation

- Large data gathering and summarising process for HPVCs
- Agreement on RA principles (TGD/EUSES)
- Agreement on priority setting (HERO)
- EU harmonised risk assessments for many controversial substances, forming the solid basis for EU wide risk reduction measures
- PBT and vPvB assessment
- IUCLID

EU accounts for 29% of the world chemicals sales in 2006 (€1.641.000.000.000)



In 2006, the EU was the world's leading exporter and importer of chemicals, accounting for half of global trade.



Solution: A New EU Chemicals Policy

Registration, Evaluation and Authorisation of Chemicals

Introduces a Single Coherent System for new (non phase-in) and existing (phase-in) substances

Solution: A New EU Chemicals Policy

- Objective: Sustainable Development
 - Protection of human health and the environment
 - Maintain/enhance innovation/competitiveness
 - Maintain the Internal Market
 - Increased transparency and consumer awareness
 - Integration with international efforts
 - Promotion of non-animal testing
 - Conformity to WTO obligations



It is estimated that
approximately
30 000 chemicals
will come under
REACH Regulation

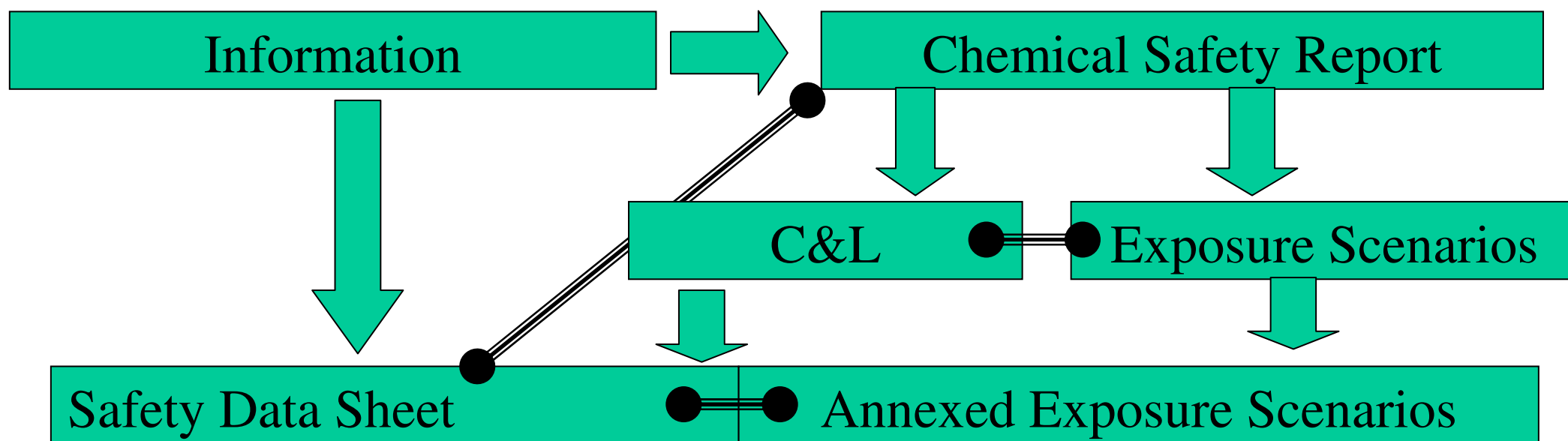


It is estimated that
approximately
**27 000 chemical
companies** will come
under the
REACH Regulation

Registration

Introduction

Industry ensures responsible and well informed management of the risk a substance may present



Design of Registration (1): Lessons Learned from New Chemicals “Notification”

- **Successes:**
 - substantial and reliable data is generated as the basis for assessing and determining appropriate risk management measures for a substance;
 - few chemicals need additional risk management measures imposed by authorities' intervention;
- **Problems:**
 - an unequal implementation
 - insufficient account of differences in the exposure;

Design of Registration (2): Lessons Learned from Existing Substances

- **Successes:**
 - The design of IT tools for large scale information gathering is possible;
 - encouraging industry to submit previously unknown data, thereby preventing unnecessary tests being performed;
 - risk management decisions based on Classification & Labelling, the results of Risk Assessment and/or the holistic approach to risk management measures can render requirements for further testing unnecessary.

Design of Registration (3): Lessons Learned from Existing Substances

- **Problems:**
 - The burden of determining if further information is needed is, in the first instance, on Member State Authorities;
 - The burden of collecting down stream exposure information on priority substances fell on manufacturers and importers;
 - Decisions on further testing of priority substances can only be taken via a lengthy committee procedure and can only be requested from industry after authorities have proven that a substance may present a serious risk.

Design of Registration (4): Lessons Learned (design of REACH)

- Minimum information set needed in REACH to enable a risk assessment to be carried out;
- Additional information should be required using a “top down approach”;
- Industry should make the proposals of which additional information is needed;
- Industry should develop and implement risk management decisions based on risk assessment (exposure scenario);
- Industry should demonstrate that no additional risk management is necessary beyond that implemented or recommended;

Design of Registration (5): REACH is part of the exposure control picture

Recall, obligations from other legislation is reflected in the Exposure Scenario:

- Restrictions;
- IPPC, IPP, Water framework Directive;
- Chemical Agents Directive;
- General Product Safety Directive.

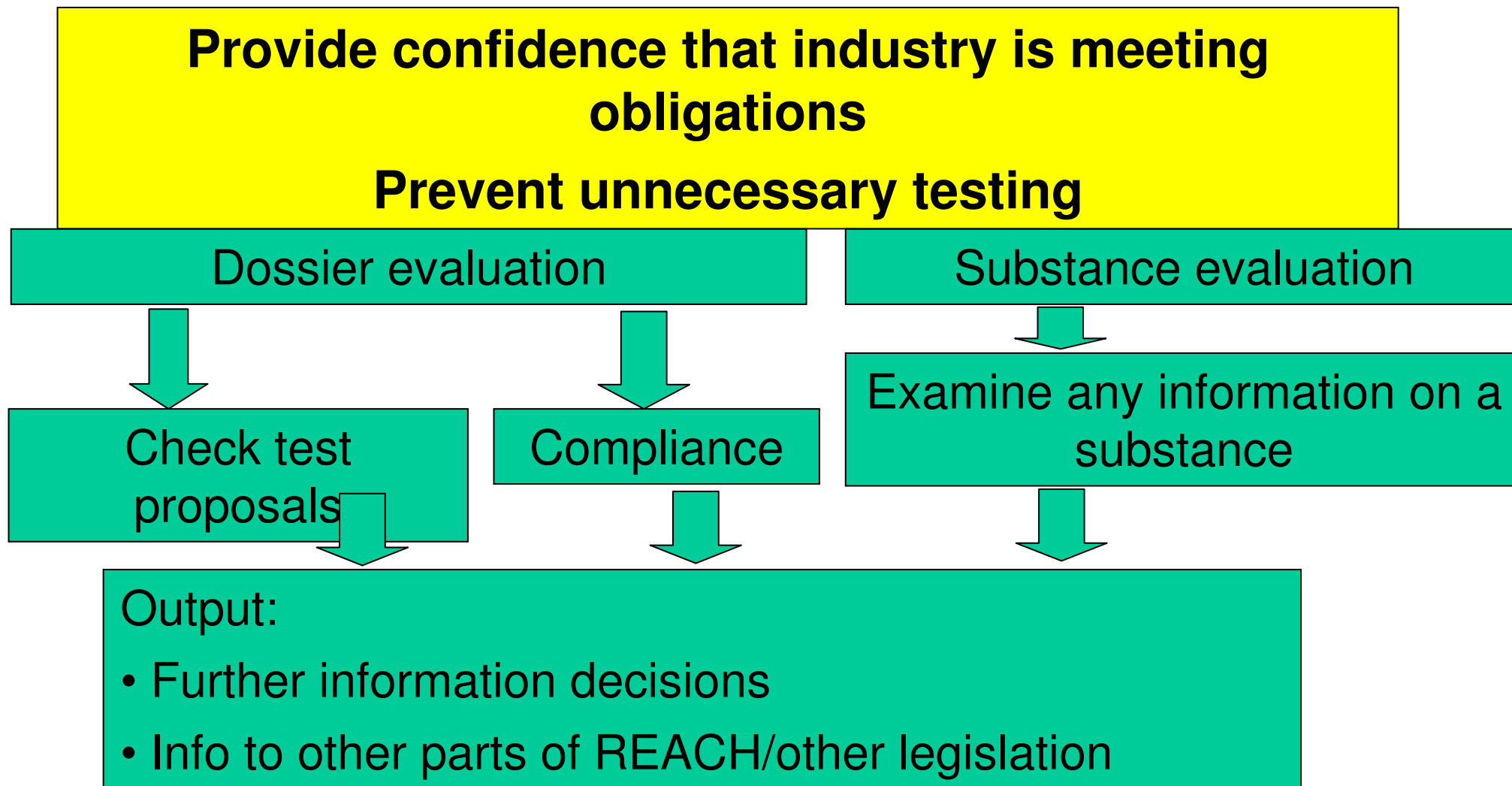
Design of Registration (6): What if industry does not quite do everything

with a security net comprising:

- Restrictions, if additional risk management is needed beyond that already applied;
- Substance Evaluation, if additional information is needed by authorities to judge if industry is ensuring responsible and well informed management of their substances.

Evaluation

REACH – Evaluation (by Agency and Member States)



Design of Evaluation (1): Lessons Learned from New Chemicals

“Notification”

- **Successes:**
 - industry implements appropriate risk management based on sufficient information;
 - authorities can enforce a specified information need clearly set out in legislation;
 - rarely any disagreement between industry over Annex VII and VIII tests.
- **Problems:**
 - The conformity check and risk assessment for notified substances :
 - is very resource intensive.
 - places responsibility on Authorities;
 - unequally implemented.

Design of Evaluation (2): Lessons Learned from Existing Substances “Conclusion (i)” Cases

- **Successes:**
 - TGD on Risk Assessment has provided a transparent and harmonised methodology;
 - A well documented dossier based on a risk assessment report provides a:
 - solid and widely accepted basis for decision making;
 - sufficient basis for defining information needs;
 - Industry developing the details of a testing proposal has proven efficient and reliable;
 - The priority setting activities have been relatively successful.

Design of Evaluation (3): Lessons Learned from Existing Substances “Conclusion (i)” Cases

- **Problems:**
 - The risk assessments have required a lot of Member State resources;

Design of Evaluation (4): Lessons Learned

- industry should define what it thinks are the information needs for their substance;
- authorities should optionally check compliance (focussed and optimised);
- priority setting to identify substances of potential concern is possible with sufficient basic information; and
- further information requests should be justified by authorities.

Design of Evaluation (5): Design of REACH

- **Dossier Evaluation:**
 - availability of the appropriate information is critical to develop risk management measures
 - correct decisions on information generation provide the best implementation of risk management for the least Authority involvement.
- **Substance Evaluation:**
 - should be carried out by a MS authority if it has reason for suspecting that a substance presents a risk
 - Agency is responsible for developing priority setting criteria

Authorisation and Restriction under REACH

Restrictions

No need for a table of contents, it all was just too slow, too cumbersome, too

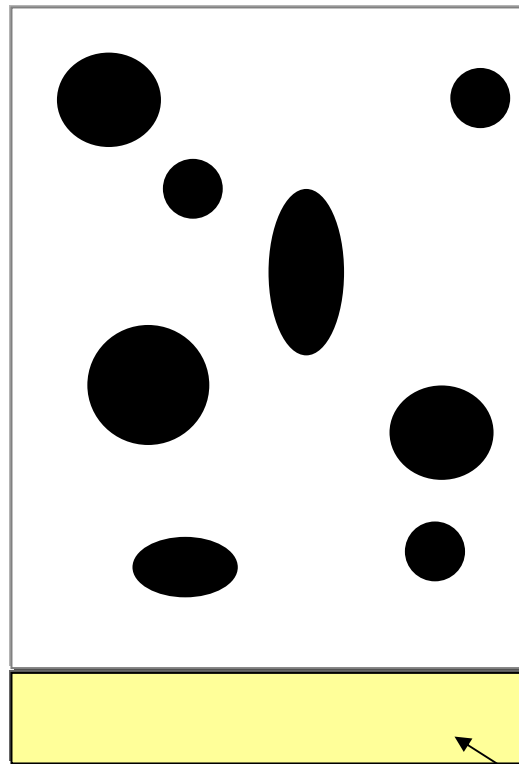
So:

- Deadlines
- Targeted Risk Assessment
- Parallel process

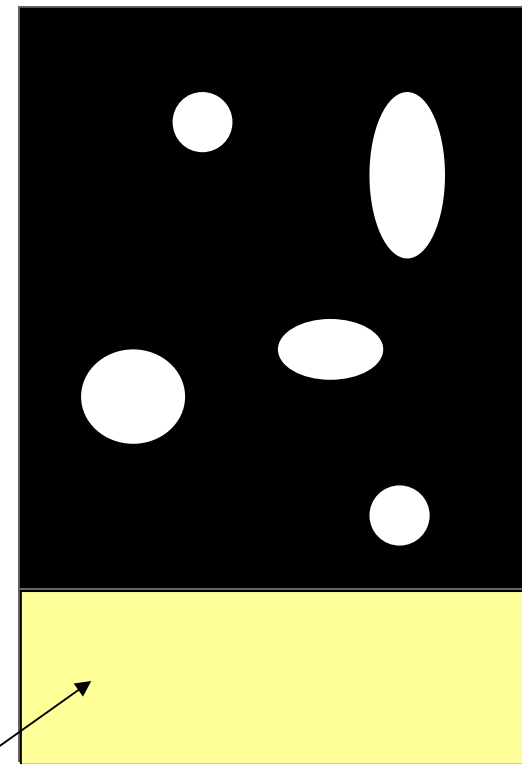
Everything of content remains more or less the same, though with another name!

Relationship between Restrictions and Authorisation

Restrictions on
Annex XVII



Authorisation on
Annex XIV



General exemptions

Conclusions

- REACH is a major overhaul of the EU chemicals legislation
- REACH is constructed to address the weaknesses and build on the strengths of previous legislation
- Shift of burden of proof to industry is key
- Major challenges ahead for all
- June 1st is 12 days from now!!!!!!!

Questions ?