



## Introduction to the New Chemicals Policy **REACH**

**REACH and Developing Countries**  
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## The Current EU Chemicals Policy

### Problems

- Existing substances can be used without testing
  - lack of knowledge about their properties and uses
- Burden of proof on public authorities
- Current system slow to act
  - no efficient instrument to deal with problematic substances
- Lack of incentives for innovation
  - in particular for less hazardous substitutes

**Burden of the Past**



## Solution: A New EU Chemicals Policy White Paper February 2001

### Objectives

- 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

**Guiding Principles - substitution and precaution**



## REACH

### One System

- Single, coherent system for new/existing chemicals**
- Elements:**
  - Registration of substances above 1 tonne
  - Evaluation by the Member States
  - Authorisation for substances of very high concern
  - Restrictions - the safety net
  - Agency to manage system
- Focus on:**
  - high volumes
  - greatest concern.

**A Tiered Approach**



## Scope

- REACH covers**
  - Manufacture, import, placing on market and use of substances
  - Substances "on their own", in preparations or in articles
- Exemptions**
  - from scope of REACH listed in Article 2
  - Specific exemptions from some parts of REACH set out in those Titles



## REGISTRATION

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## Registration

- ❑ **AIM**  
Manufacturers and importers obtain information on their substances and use this knowledge to ensure responsible and well-informed management of the risks the substances may present
- ❑ **Registration Dossier = Documentation**
  - Technical Dossier: starting at 1 tonnes per year
  - Chemical Safety Report: starting at 10 t per year

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## Registration: general

Ensure industry adequately manages the risk from its substances

- ❑ **Method:**
  - manufacturer/importer obtains adequate information;
  - > 10 tonnes/year: performs chemicals safety reports (inc RRM)
  - electronic submission to Agency (completeness check)
  - certain non-confidential information in central, largely public, database.
- ❑ **Scope**
  - substances produced/imported > 1 tonne/year
  - intermediates - reduced requirements.
  - exemptions - other law, Annex II/III; polymers (review); PPORD
  - deemed as Registered - biocides, pesticides, notified substances (67/548)
- ❑ **Consortia encouraged**

No formal acceptance necessary - industry retain responsibility

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## Product and Process Orientated R&D

- ❑ Wide definition
- ❑ 5-year exemption – notification required
- ❑ 4 weeks delay before manufacture or import
- ❑ Agency may impose conditions
- ❑ Extension by up to 5 years/up to 10 years for medicines
- ❑ Decisions by Agency
- ❑ MS Competent Authorities comment on draft decisions
- ❑ All information treated as confidential

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## Registration: information

- ❑ **Information requirements - smart/targeted:**
  - exposure often taken into account.
  - new testing as a last resort – existing data, (Q)SAR, read across.
- ❑ **Low volume chemicals (1-10 tonnes/year):**
  - mostly in-vitro.
- ❑ **Higher volume chemicals:**
  - testing only if existing information/validated alternative methods not sufficient.
  - Testing programmes - agreed by the competent authorities

REACH = large-scale information collection, ~~large-scale testing.~~

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## Registration: Deadlines

| Tonnage Range | Deadline |
|---------------|----------|
| >1000 t + CMR | Yr 0     |
| 100 - 1000 t  | Yr 0+3   |
| 1 - 10 t      | Yr 0+6   |
| SIA           | Yr 0+11  |

2017+

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## Information Requirements

### TECHNICAL DOSSIER

- ❑ Common information for all registrations
  - Annex IV
- ❑ Depending on tonnage threshold
  - > 1 t/yr ⇨ Annex V
  - > 10 t/yr ⇨ As above + Annex VI
  - > 100 t/yr ⇨ As above + proposals for Annex VII
  - > 1000 t/yr ⇨ As above + proposals for Annexes VII and VIII

### CHEMICAL SAFETY REPORT (CSR) if > 10 t/yr



## Registration: Testing Annexes

### Annex V

- Physicochemical properties
- Basic human health data (4 end-points)
- Short term aquatic toxicity
- other available information

### Annex VI

- Human health data (including *in vivo*)
- Ecotoxicological data

### Annex VII and Annex VIII

- Long term, repeat dose, chronic, fate etc

**Exemptions** built into Annexes V to VIII

**General Rules** for exemptions in Annex IX



## Generation of Information

### Annex IX = FLEXIBILITY

- (Q)SARs
- Use of category approaches
- Analogs, read across
- Available data (non-EU, GLP, non-GLP)
- Exposure based waiving (Annexes VII and VIII)
- Historical human data
- Data sharing (existing and new)

**Testing (*in vitro*, *in vivo*) as a last resort**



## Chemicals Safety Assessment

- ❑ To be performed for all substances (per substance or per group of substances) subject to registration if **above 10 tonnes/** per year Per substance or per group of substances
- ❑ To be **documented in a Chemical Safety Report**
  - Part of the registration dossier
- ❑ **Exemptions** for substances in preparations below certain concentration limits
- ❑ **Defined in Annex I**
- ❑ **Includes**
  - Human health hazard assessment
  - Environmental hazard assessment
  - PBT and vPvB assessment



## Role of the Agency in Registration

- ❑ **Completeness check**
- ❑ **Further information to Agency by deadline**
- ❑ **Deadline missed = registration rejected**
  - ➔ **no registration: manufacture or import not allowed**
- ❑ **Appeal possible**
- ❑ **Information to relevant MS CA**



## Downstream Users (DU)

- ❑ **Manufacturer/importer** registration to cover all uses identified by downstream users
- ❑ **DU must**
  - implement supplier's RRM for identified uses
- ❑ **DU need to:**
  - enter into dialogue with their suppliers
  - consider consortia building and/or cost sharing
- ❑ **DU may need to apply for authorisation**



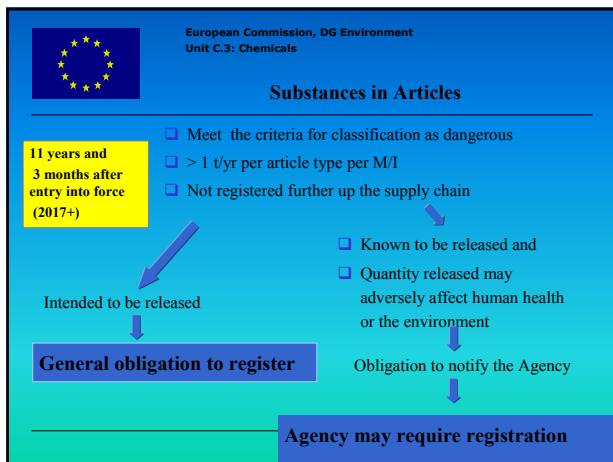
## DU's Rights and Duties

### CSA: choice for downstream users

- Right to make a use known to his supplier
  - ⇨ supplier performs the assessment
- Choice to keep his use confidential:
  - ⇨ duty to perform a CSA only if his use is not covered in the SDS supplied to him

### Duty to report information if (>=1 tonne)

- his use is not covered in the SDS supplied
- he applies or recommends different RMM



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# DATA SHARING

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### Data sharing

Avoidance of unnecessary animal testing + save costs

- Information > 10 years – freely available
- Non-phase-in substances (= new):
  - Already registered?
  - Agency enables contact - 50% cost sharing
  - Studies involving vertebrate animals not repeated
- Phase-in substances (= existing):
  - Potential registrants of same substance: 'SIEF'
  - Sharing mandatory (vertebrate animals), if participant refuses to share = sanctions
  - Equal sharing of costs

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### Consortia

| Individual  | Choice   | « One for all »  |
|---|--|--|
| Identity of M/I<br>Identity of the substance<br>Information on manufacture and use<br>Statement whether information has been generated by testing on vertebrate animals | Guidance on safe use<br><br>Chemical Safety Report | Summaries or robust study summaries of information derived from application of Annexes V bis IX<br><br>Proposals for testing where required by application of Annexes V bis IX<br><br>Classification and labelling |

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### Details for non phase-in (new) substances

- Potential registrants consult database and Agency: Is same substance registered?
- Agency enables contact with previous or other potential registrants
- Studies involving vertebrate animals shall not be repeated
  - Registrants shall take all reasonable steps to reach an agreement on the access to available information
  - If not: Agency shall make summaries available to potential registrant, previous registrant gets 50% of the cost and may request that waiting period is extended
- Other studies: potential registrants may ask for information that previous registrants are willing to share

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### Details for phase-in substances

**Pre-registration ⇔ database**

- Potential registrants submit info on available studies at the latest after 1,5 (> 1000t) or 4,5 yrs (> 1t)
- Contributions by DU and M/I < 1t possible

**SIEF = Substance Info Exchange Forum**

- Potential registrants of same substance
  - ⇔ Access to database for that substance

**Within SIEF**

- Aim: exchange info to minimise duplication of tests
- Study not available: participants agree who performs it
- Study available: participants agree on sharing cost, otherwise equal shares
- Sharing of tests involving vertebrate animals mandatory
  - if participant refuses to share => sanctions
  - testing allowed by rest of SIEF

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# INFORMATION THROUGH THE SUPPLY CHAIN AND DOWNSTREAM USERS

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## Information through the supply chain

Encourage communication → Improve risk management

- ❑ **Information down the supply chain**
  - SDSs for classified substances with information from CSR (exposure scenarios) in Annex
  - Information for non classified substances on authorisations, restrictions, registration number etc. to enable RMM to be identified and applied
- ❑ **Information up the supply chain** on new hazards and if received info is challenged
  - more information on risks
  - downstream users benefit

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## Information through the supply chain

Improve risk management


- ❑ **What?**
  - Expanded SDSs – info from Chemical Safety Reports
    - Exposure scenarios as Annex
  - Information on authorisations, restrictions, registration number etc.
- ❑ **Result?**
  - more information on risks
  - downstream users brought into the system
  - dialogue up/down the supply chain - encouraged/stimulated

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# EVALUATION

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## Evaluation

### Dossier evaluation

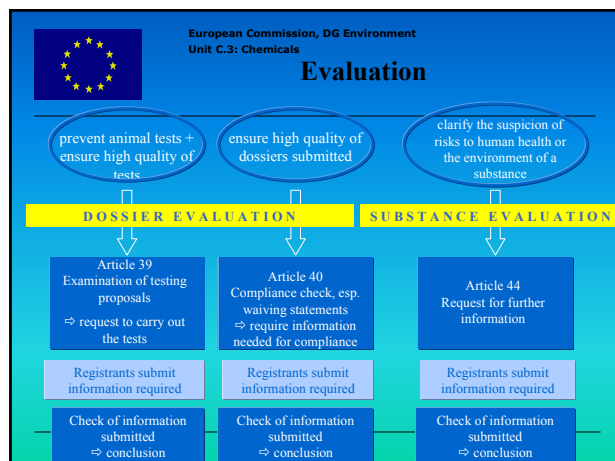
- CA from MS where registrant is based
- Examination of testing proposals
- Compliance check

### Substance evaluation

- MS prepare rolling plans
- Mechanism to select one CA if several MS want to evaluate
- Follow-up suspicion of risk: request more info

### Agency

- Sets priorities
- Takes decisions if all MS agree (else comitology)





# AUTHORISATION



## Authorisation

**AIM: Ensure risks from substances of very high concern are properly controlled or that they are substituted.**

- CMR, PBT, vPvB, 'serious and irreversible effects';
- Prioritised (progressively authorised as resources allow);
- Applicant to show:
  - adequate control of risks, or
  - social and economic benefits outweigh the risks
- Socio-economic authorisation - normally time-limited
  - substitution plan considered
- DU can use suppliers authorisation
- Other M/I may get a letter of access to an authorisation



## Authorisation

**Substances of very high concern that may be included in the authorisation system:**

- (a) Carcinogenic substances, cat. 1 and 2
- (b) Mutagenic substances, cat. 1 and 2
- (c) Reprotoxic substances, cat. 1 and 2
- (d) PBTs (Annex XII criteria)
- (e) vPvBs (Annex XII criteria)
- (f) causing serious, irreversible effects to humans or the environment which are equivalent to those listed under (a) to (e)

Art. 56 procedure case-by-case decision



## Authorisation: Inclusion of a substance in Annex XIII

### Pool of substances

- **Agency:** Recommendation of priority substances
- **Interested Parties:** comments on properties and uses to be exempt
- **Commission:** regulatory committee procedure
  - Annex XIII specifics**
    - identity of substance + intrinsic properties
    - sunset date and application date
    - exemptions for specific uses + conditions
    - appropriate review periods



## Authorisation: Exemptions

- General** exemptions for specific uses:
  - e.g. biocides, pesticides → Art. 53
- Substance specific** exemptions:
  - When including a substance in Annex XIII or later when the Annex is changed
  - Account shall be taken of existing Community legislation
  - Exemptions may be subject to conditions
    - ⇒ harmonised risk management standards
    - = effect is the same as a restriction for this use



## Authorisation: Application

- to be submitted to the Agency
- grouping of substances or uses
- required information:
  - identity of substance + applicant
  - if not registered: **Chemical Safety Report** covering the risks triggering inclusion in Annex XIII and only the uses applied for
- optional information:
  - socio-economic analysis
  - analysis of the alternative substances or technologies



## Authorisation: Procedure for decisions

- Agency's **RA Committee** and **SEA Committee**: draft opinions, based on
  - Information contained in the application
  - Information from third parties on alternative substances or technologies
- Applicant**: comment on the draft opinions
- Committees**: final opinions, non-confidential parts to be published on website
- Commission**: decision taken in advisory committee procedure



## Authorisation: Granting

- COM shall grant an authorisation if the risks are adequately controlled as documented in the CSR
- If not, it may be granted if the socio-economic benefits outweigh the risk and if there are no suitable alternative substances or technologies



## Authorisation: Decision

- person to whom authorisation is granted
- identity of the substance
- use(s) for which an authorisation is granted
- any condition under which the authorisation is granted
- any review period
- any monitoring arrangements



## RESTRICTIONS



## Restrictions

### Safety net

- Community wide concern
- MS/COM initiated
  - Fast track possible e.g. CMR substances for consumers
- Agency Committees examine:
  - the risk, and
  - the socio-economic aspects involved
- Commission - final decision through comitology
- Carry-over of existing restrictions (76/769/EEC)
- POPs



## CLASSIFICATION AND LABELLING



## C and L

- ❑ **Current legislation:**
  - C&L all substances placed on market;
  - some substances harmonised in Annex I of 67/548
- ❑ **Inventory:**
  - managed by Agency
  - contains C and L info for all marketed substances:
    - no tonnage limit
  - deadlines – 3 years
  - supplied through registration or separately
- ❑ **Industry co-operate** to resolve differences in C&L
- ❑ **EU harmonisation:**
  - CMRs
  - respiratory sensitisers



## C and L: GHS

- ❑ **GHS not included** in current proposal
- ❑ **Studies on differences and impact on down-stream legislation** carried out
- ❑ **Implementation foreseen next phase**
  - Proposal for a regulation either part of REACH or separate
  - Will replace 67/548 and 99/45



## CONCLUSIONS



## Current legislation vs REACH

- ❑ **Burden of Proof on authorities**
  - Little possibility to require industry to come forward with information on properties of substances. Except
    - New substances notified
    - For priority substances in existing substances progr.
- ❑ **No information on uses**
- ❑ **C and L, harmonised for about 3000 substances**



## Current legislation vs REACH

- ❑ **Burden of proof on Industry**
  - Registration of all chemicals
    - ⇒ knowledge on properties and uses increases
  - Authorisation for high concern chemicals
  - C and L, harmonised for fewer substances, but better information on self classification through Inventory
- ❑ **Quicker restrictions (Burden of Proof not revised)**
  - Comitology, simpler MS proposals
- ❑ **Central Agency**



## Conclusion - REACH will ensure:

- ❑ **High level of protection**
- ❑ **Burden of proof on those creating risks**
  - better use of resources
- ❑ **Improved knowledge**
  - information for downstream users
- ❑ **Improved innovation**
- ❑ **Substitution of dangerous substances**
  - particularly through authorisation
- ❑ **Better:**
  - reaction to emerging risks
  - consumer confidence

**Benefits significantly outweigh costs**