

Principles of REACH

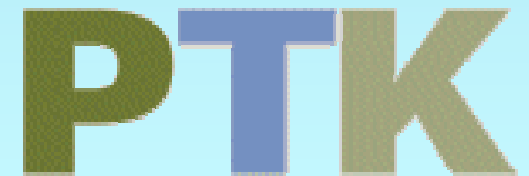
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Protection Through Knowledge

Why I am here

- **PTK Ltd: consultancy on regulatory chemicals issues (e.g. REACH, GHS, SAICM)**
- **DG ENTR (until September 2004)**
 - author (1 of) of REACH
 - co-decision process (Council & EP)
 - implementation of GHS in EU
- **UK government (HSE): international chemicals policy**
 - policy on chemicals strategy White Paper
 - author (1 of) of GHS: IOMC drafting group
 - Acting head of UK delegation to IFCS III
- **DG ENV chemicals unit (94 – 97)**
 - NONS, ESR, C&L

Presentation

- Why do we need REACH?
- The solution
- What is REACH?
 - **Scope**
 - **Registration**
 - **Evaluation**
 - **Restrictions**
 - **Authorisation**
 - **Information**
- Progress in co-decision
- Interim Strategy

Why do we need REACH?

Problems

Current chemicals management system is inefficient

- **Difficult to identify risks – difficult to address risks:**
 - Lack of information about most substances on the market
 - Burden of proof on public authorities
 - No efficient instrument to deal with problematic substances
- **Lack of incentives for innovation**
- **Lack of confidence in chemicals**

Burden of the Past

Lack of Information

- Lack of hazard data for most substances on the market:

No 'Official' Data (20% of number)	Limited Data (45%)	Base Set (20%)	Level 1 (10%)	Level 2 (5%)
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- Unknown volumes & uses of most substances on the market
- Incorrect C&L & SDS:
**only 20% of substances & preparations in full compliance;
20% of errors for preparations 'severe'**

Why do we need REACH?

- Environment barometer survey:
 - 35% concerned about impact of chemicals in everyday products (5th)
 - 41% feel they lack information on chemicals (1st)

<http://europa.eu.int/comm/environment/barometer/index.htm>

- Recent US case over non-disclosure of evidence of serious human health effects:
Manufacturer fined \$16.5 million for covering up studies showing chemical released to the environment potentially causing cancer, birth defects and other serious health problems in animals.

Solution: A New EU Chemicals Policy

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
 - Conformity to WTO obligations

Substitution and precaution underpin system

What is REACH?

High level of health and environmental protection with the goal of achieving sustainable development.

- Single coherent system for new (non phase-in) and existing (phase-in) chemicals
- Elements:
 - Registration of substances ≥ 1 tonne/yr (staggered deadlines)
 - More information and better communication through the supply chain
 - Evaluation of some substances by European Chemicals Agency (MS support for substance evaluation)
 - Authorisation only for substances of very high concern
 - Restrictions - the safety net
 - Agency to manage system
- Focus on priorities:
 - high volumes (early deadline)
 - greatest concern (CMRs and high volume R50/53 early)

A Tiered Approach

Scope

- **General exemptions:**
 - Waste and food fully exempted
 - Non-isolated intermediates
- **Worker and environmental legislation applies without prejudice to REACH**
- **Exemptions from Registration**
 - Uses covered by sectoral legislation (e.g. medicinal uses, food additives)
 - Identified individual substances (Annex II)
 - E.g. some organics, cellulose pulp
 - Categories of substance (Annex III). For example:
 - Ores, ore concentrates, minerals exempted unless chemically modified
 - Cement clinker, LPG, crude oil, coke, coal unless chemically modified.

Pre-registration

- **Pre-registration – 18 months after EIF (+ 6 months by DU if substance not pre-registered by M/I)**
- **What?**
 - Substance name, potential registrant details (or 3rd party representative), deadline for registration, similar substances (for read-across).
- **Agency publishes list of information on website**

Registration: general

Registrant collects information, assesses risk(s) and implement/recommend relevant control measures

- **Scope**
 - substances produced/imported ≥ 1 tonne/year
 - Isolated intermediates: reduced requirements.
 - Exemptions e.g. PPOORD, polymers, non-isolated intermediates
- **Tasks of the registrant (manufacturer/importer (only rep.)):**
 - obtain adequate information (inc (Q)SAR and existing data)
 - perform CSA for substances > 10 tonnes/year (demonstrate adequate control per use)
 - send information to Agency by deadline (and to clients)
- **One Substance One Registration (OSOR) (Pre-registration – 18 months)**

No formal acceptance - industry retain responsibility

Registration: Timing

Volume of substance produced or marketed (per manufacturer or importer)	Registration period for existing substances (Deadlines in Bold) (assuming 2007 start)
≥ 1,000 tonnes p.a. or CMR or PBTs/vPvBs (R50/53)>100t p.a.	2007 - 2010
100 – 1,000 tonnes p.a.	2010 - 2013
10 – 100 tonne p.a.	2013 - 2018
1 tonne p.a.	2013 - 2018

High data



CSRs



'Screening'

Intelligent Testing Strategies

Registration: OSOR

- Pre-registration – 18 months after EIF
- Data sharing
 - Animal data always shared
 - Non animal data shared on request
- Joint data submission: mandatory with opt outs:
 - Disproportionate cost
 - Commercial secrets
 - Disagreement on selecting data

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

Generation of Information

- (Q)SARs
- Use of category approaches
- Analogs, read across
- Available data (non-EU, GLP, non-GLP)
- Historical human data
- Data sharing (existing and new)
- Testing (*in vitro*, *in vivo*) as a last resort

See Annex IX = FLEXIBILITY !

- **Information requirements may also be waived**
 - because testing can't be done on a substance
 - for some tests (mainly in Annexes VII and VIII) because of no/limited exposure (exposure based waiving)

Registration: 1 – 10t

- 1-10 tonnes
 - All: physicochemical properties of Annex V (+ available information).
 - New substances: full Annex V (extended)
 - Screening by registrant:
 - likely CMR, PBT or vPvB, or
 - Dangerous for health and environment plus widespread exposure?
- => full Annex V (extended)

Registration: Substances in articles (1)

- Registration of substances intentionally released (Art. 6.1)
 - applies to all SIA (i.e. no requirement to meet criteria for classification as dangerous)
 - deadlines as other substances

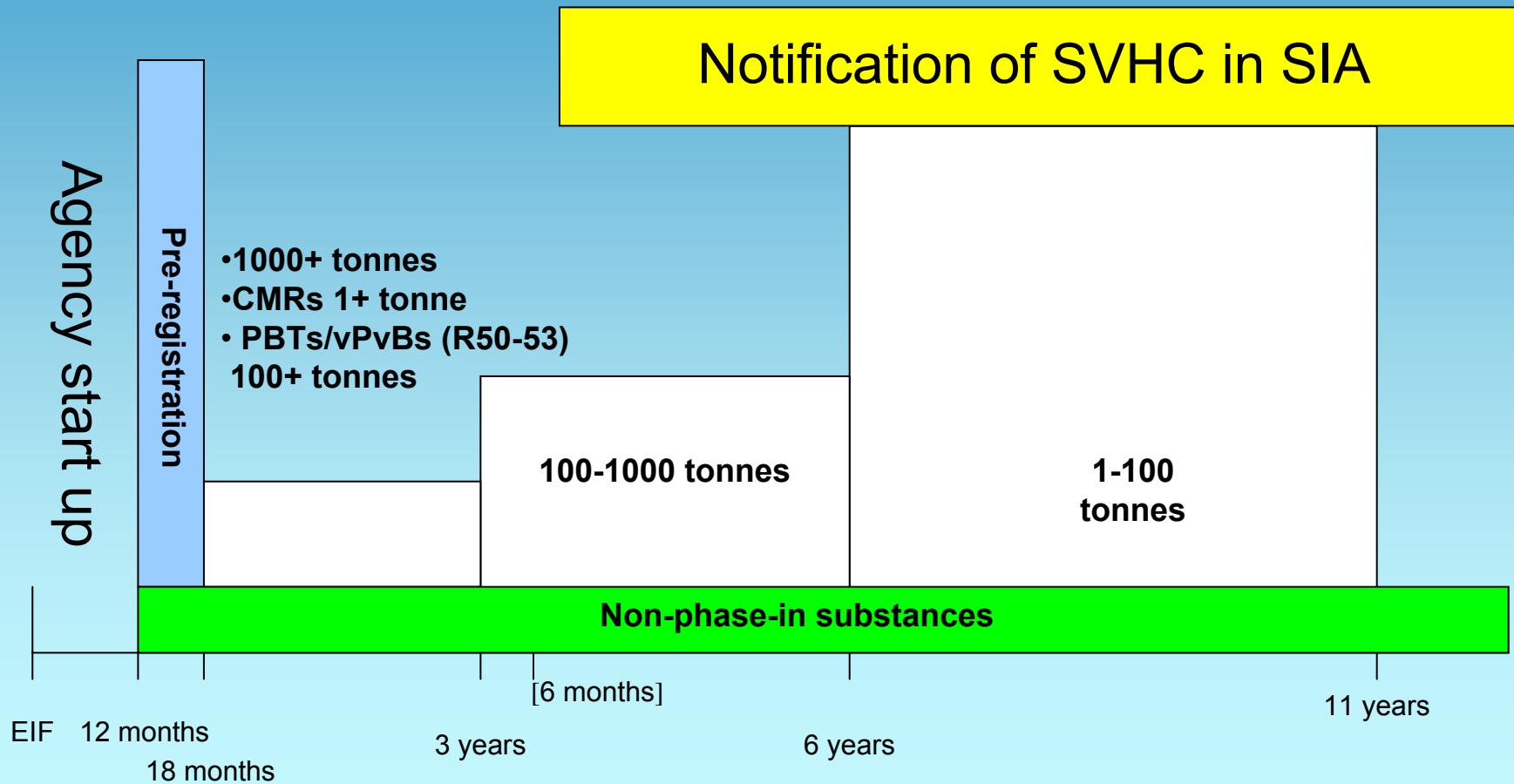
Registration: Substances in articles (2)

- **Notification of substances of very high concern (Art. 6.2) if:**
 - present above a concentration limit of 0,1%,
 - exposure of the public or the environment during the full life cycle cannot be excluded,
 - it is present above 1 tonne
- **applies 6 months after substance listed on authorisation candidate list – i.e. only commences 3 years and 6 months after EIF**

Registration: Substances in articles (3)

- **Agency can request registration of any notified substance contained in articles, when:**
 - Substance is present over 1t; AND
 - Suspects that the substance is released and that release presents a risk to human health or the environment; AND
 - Substance is not subject to Art. 6.1

Registration: Overview



Information through the supply chain

Improve risk management

- **What:**
 - Expanded SDSs with information from Chemical Safety Reports (CSR) - **exposure scenarios**
 - Information on risk management, authorisations, restrictions, registration number etc.
 - Information up the supply chain on new hazards
- **Result?**
 - more information on risks
 - downstream users benefit
 - dialogue up/down the supply chain- encouraged/stimulated

Downstream Users (DU)

- **Manufacturer/importer CSR to cover all uses identified by downstream users.**
- **DU benefit from choice of:**
 - supplier carrying out assessment, or
 - for confidentiality reasons doing own assessment.
- **If using suppliers CSR just have to:**
 - implement supplier's RRM for identified uses
- **If carrying own CSR (>1t) will have to:**
 - perform assessments only for 'unidentified uses' (using supplier hazard information)
 - inform Agency of 'unidentified uses'

Evaluation

Provide confidence that industry is meeting obligations

Prevent unnecessary testing

Dossier evaluation

Substance evaluation

Check test proposals

Compliance

Examine any information on a substance on CRP

Output:

- Further information decisions
- Info to other parts of REACH and other legislation

Evaluation (2)

- **Agency responsible for:**
 - dossier evaluation
 - test proposals and
 - 5 % + conformity checks
 - establishing draft Community rolling plan (CRP) for substance evaluation
 - substance evaluations (but will rely on MS CA and expertise)

Restrictions

Safety net

- **Community wide concern**
- **MS or COM initiated (Annex XIV dossier)**
- **Agency Committees examine:**
 - the risk, and
 - the socio-economic aspects involved
 - 3rd party comments
- **Consumer use CMR substances - fast track possible.**
- **Commission - final decision through comitology**
- **Carry-over of existing restrictions (76/769/EEC)**

Authorisation

Ensure risks from substances of very high concern are properly controlled and eventually substituted

- **Applies to:**
 - CMR, PBT, vPvB
 - ‘equivalent concern substances with scientific evidence of probable serious effects’ e.g. EDS
- **Prioritised (progressively authorised as resources allow)**
- **Commission grants authorisations**
- **DU can use suppliers authorisation or apply for their own**

Authorisation (2)

- Criteria for granting authorisations:
 - Authorisation granted if adequate control
 - Not available for PBT, vPvBs or CMRs/substances of equivalent concern if not possible to determine a threshold.
 - Still possible to grant authorisation if socio-economic benefits outweigh the costs
 - Analysis of substitutes in all cases.
- Public list of substances to be authorised (eventually):
 - Published by Agency
 - Candidate list: substances meeting criteria
 - Annex XIII (substances prioritised and picked for authorisation within set timeframe)

Information

- **Published information (art 116)**
 - Published on web, free of charge:
 - Information on substance identity,
 - classification,
 - physicochemical data,
 - results of toxicological and ecotoxicological studies,
 - DNELs, PNECs,
 - guidance on safe use,
 - analytical methods.
 - Published on web, free of charge, unless companies justify otherwise:
 - Information on tonnage bands,
 - impurities,
 - information in the SDS (unless above)
 - study summaries/robust study summaries.

Key Elements

- **Better information**
- **Joined up supply chain**
- **Industry responsibility for safe management**

Start-up*

- **20 days after entry into force (EIF):**
 - Titles I (general issues), IV (ISC), XII (CAs), XIII (enforcement), XIV (transitional) commence;
 - N.B. MS enforcement law by 18 month after EIF.
- **12 months after EIF:**
 - Agency opens doors in Helsinki, FIN;
 - Titles II (registration), III (data sharing), V (downstream users), VI (evaluation), VII (authorisation), X (C&L inventory) and XI (information) commence;
 - Existing legislation (new/existing substances applies until then).
- **18 months after EIF new restrictions apply.**

*based on Council political agreement

Progress in co-decision

<u>Commission:</u>	Proposal 29 October 2003
<u>Parliament:</u>	First reading: 17 November 2005
<u>Council:</u>	Political agreement by unanimity: 13 December 2005

- 2006:
 - Common Position (early summer)
 - 2nd reading in Parliament (late Autumn)
 - conciliation?
- 2007 **Entry into force**
- 2008 **Agency starts**
- 2010 **First Registration deadline**

Commission's Interim Strategy

- **Commission's practical preparations**
 - Before REACH coming into force: Jan 2004 – 2006
 - In co-operation with industry and MS
- **REACH Implementation Projects (RIPs):**
 - RIP 1: Process descriptions (available on ENV website)
 - RIP 2: Development of IT systems (REACH-IT)
 - RIP 3/4: Guidance Documents (industry/authorities)
 - RIP 5/6: Preparation for start-up of Agency
 - RIP 7: Commission preparations
- **Strategic partnerships (SPORT, PRODUCE)**

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PTK

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