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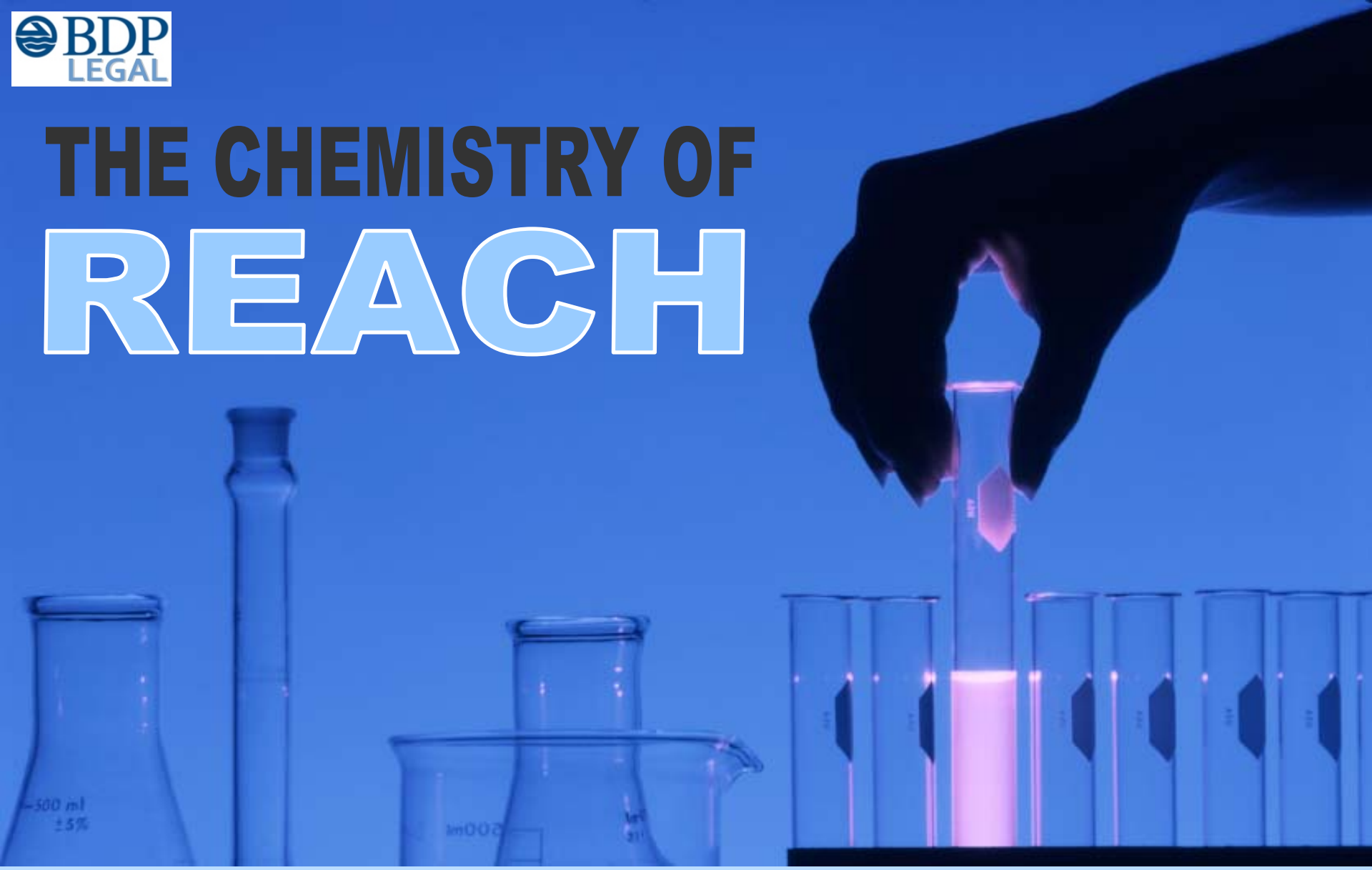
THE CHEMISTRY OF REACH



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CHEMICALWATCH
Briefing businesses on REACH and chemical risks

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BARLOW LYDE & GILBERT

AGENDA

THE CHEMISTRY OF REACH

1) Background of REACH: The Goal, Scope & Impact of this New Regulation
2) Current Events Analysis: Tracking the Progress of REACH Compliance
3) An Industry Leader Speaks: Strategies for REACH Compliance
4) On the Enforcement Horizon: What Are Your Risks?
5) Q&A Session

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THE CHEMISTRY OF REACH

Background of REACH: The Goal, Scope & Impact of this New Regulation

Malachy Hargadon, Environment Counselor
Delegation of the European Commission

What is REACH?

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- **Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 on the Registration, Evaluation and the Authorisation of CHemicals**

- **Scope:**
  - **manufacture, import, placing on market and use of substances (on their own, in preparations or in articles)**

- **Goals:**
  - **Improving health and safety of workers and the general public**
  - **Environmental protection – avoiding chemical contamination of air, water, soil and damage to biodiversity**
  - **Maintaining a competitive/innovative chemicals industry**

Key elements of REACH

THE CHEMISTRY OF REACH

- **Registration of substances ≥ 1 tonne/yr**
- **Evaluation of some substances**
- **Authorisation only for substances of very high concern**
- **Restrictions - the safety net (Community wide action)**
- **Agency to efficiently manage system**

Focus on priorities:
Substances with high volumes and those of greatest concern!

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Registration

THE CHEMISTRY OF REACH

AIM: Ensure industry adequately manages risks from substances

- **What?**
  - **Tonnage based**
  - **Registration deadlines: 3½-6-11 years**
  - **Limited information for intermediates and exemption for polymers**
  - **Limited information for research and development (PPORD)**
  - **Substances in articles**
- **How?**
  - **Manufacturer/importer obtains or generates adequate information**
  - **Electronic dossier submitted to Agency**
  - **Certain non-confidential information to central (largely public) database.**

Industry's responsibility

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Registration Requirements

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	Health	Environment
1-10t prioritised	❑ *In vitro* skin and eye irritation ❑ Skin sensitiation ❑ *In vitro* mutagenicity ❑ Acute toxicity (one route)	❑ Acute aquatic toxicity – Daphnia ❑ Biodegradation – biodegradability and hydrolysis ❑ Acute aquatic toxicity – Algae
10-100t	❑ *In vitro* skin and eye irritation ❑ Further *in vitro* mutagenicity ❑ Sub acute toxicity (28 days) ❑ Reproductive toxicity screen	❑ Acute aquatic toxicity – Fish ❑ Activated sludge ❑ Adsorption/desorption screening
100-1000t	❑ Further mutagenicity tests ❑ Sub-chronic toxicity (90-days) ❑ Further reproductive toxicity tests	❑ Long term aquatic toxicity daphnia and fish ❑ Further degradation and fate/behaviour studies ❑ Short term effects on terrestrial organisms
>1000t	❑ Further mutagenicity tests ❑ Carcinogenicity ❑ Chronic toxicity ❑ Further reproductive toxicity tests	❑ Further degradation and fate/behaviour studies ❑ Long term effects on terrestrial organisms

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Pre-Registration

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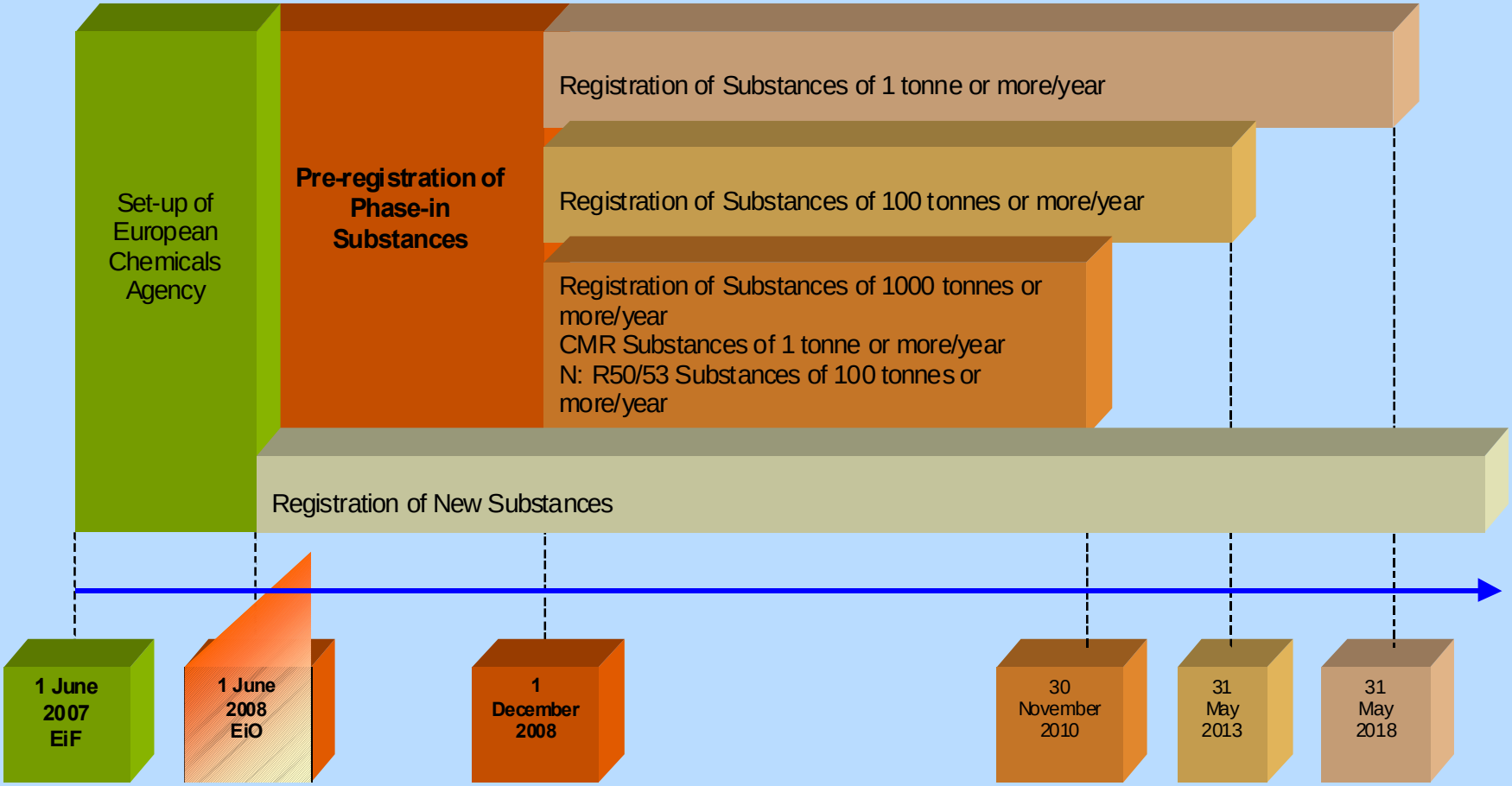
- At the end of the pre-registration period:
  - 65,000 companies from all 27 MS + EAA (85% as SME)
  - 2,750,000 pre-registrations received
  - 146,000 different substances pre-registered
    - Complete EC inventory
    - 17,000 identified by CAS numbers
    - 9,500 identified by chemical names
    - 14,500 multi-constituent substances (Reaction mass)
  - Updated list of pre-registered substances published at end of March

REACH Timeline

THE CHEMISTRY OF REACH



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Evaluation

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- **Dossier evaluation**
  - **By public authorities**
  - **Examination of testing proposals**
  - **Compliance check**

- **Substance evaluation**
  - **Rolling plans with substance prioritisation**
  - **Follow-up suspicion of risk: request more info**

Authorities' responsibility

Authorisation

THE CHEMISTRY OF REACH

AIM: Ensure risks from substances of very high concern (SVHC) are properly controlled and eventually substituted

- Applies to
  - SVHC (CMR, PBT, vPvB, 'scientific evidence of probable serious effects')
  - Substance, substance in preparation (unless below concentration limit), substance incorporated into an article
- Substance cannot be used unless authorised
- Prioritised - Substances progressively authorised (as resources allow)
- Downstream Users can use suppliers' authorisation

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Authorisation process - steps

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1. Identification of Substances of very high concern
2. Inclusion in Candidate list (first one 15 substances)
3. Draft Recommendation on Priority substances for authorisation
4. Commenting period (3 months, 1st round until 14 April)
5. CHA Recommendation to Commission by 1 June 2009
6. Commission decision = inclusion in Annex XIV
    - application date
    - sunset date

- First decision expected end 2009 or early 2010

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Restrictions

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AIM: act as 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)**

European Commission's responsibility

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REACH for non-EU companies

THE CHEMISTRY OF REACH

- Non-EU companies are not directly impacted (i.e. do not have direct legal obligations)
  - but imports to the 27 EU-Member States are under the scope of REACH
- EU-importers or Only Representatives (O.R.) must fulfill all REACH obligations for imported substances, preparations, articles, such as:
  - (pre-) registration, including data exchange (SIEF)
  - notification of SVHC in articles if above 0.1% SVHC in articles:
    - notification to ECHA (2011)
    - info for downstream users (when introduced on the Candidate list)
    - info to consumer on request (when introduced on the Candidate list)

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Focus on Only Representatives

THE CHEMISTRY OF REACH

- The non-EU manufacturer shall
  - inform the importers within the same supply chain of the appointment
  - provide the O.R. with all necessary information
    - Hazard data, incl. test data
    - Information on all importers and their subsequent supply chains (exposure scenarios)
    - Presence of SVHC at >0.1% in articles
    - All information needed for preparing/updating a SDS
- Without good and complete data from the Exporter, the importer or O.R. cannot function!

Current Issues

THE CHEMISTRY OF REACH

- Forum for Exchange of Information on Enforcement
- Substance Information Exchange Fora (SIEFs)
- REACH-IT

European Chemicals Agency in Helsinki

THE CHEMISTRY OF REACH

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European Chemicals Agency

THE CHEMISTRY OF REACH

- Agency set-up on 1 June 2007
- Technical, scientific and administrative aspects of REACH:
  - Registration – accept, reject or require completion of registration
  - Evaluation - carry out dossier evaluation, responsible for substance evaluation, ensure a harmonised approach, take decisions
  - Authorisation/Restrictions - facilitate process, suggest priorities
  - Secretariat for Forum and Committees
  - Deal with appeals - registration, R&D, evaluation, confidentiality
  - Finalise guidance documents (RIPs)

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European Chemicals Agency

THE CHEMISTRY OF REACH

- Executive Director
  (Management Board voted in October)
- Management Board (governing body of the ECHA)
- Secretariat supports Committees and Forum
- Member State Committee
  (arbitrates differences of opinions and proposes SVHC)
- Risk Assessment Committee
  (opinions on evaluation, applications for authorisation, proposals for restrictions and C&L)
- Committee for the Socio-Economic Analysis
  (opinions on applications for authorisation, proposals for restrictions and questions relating to the socio-economic impact of proposed legislative action
- Forum (enforcement)
- Board of Appeal

European Chemicals Agency

THE CHEMISTRY OF REACH

- ECHA Helpdesk
- Advice and assistance to manufacturers and importers (for Registration)
- Support to the helpdesks established by Member States
  - http://ec.europa.eu/echa/reach/helpdesk/echahelp_en.html

- National helpdesks
  - http://ec.europa.eu/echa/reach/helpdesk/nationalhelp_contact_en.html

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Stakeholder's involvement

THE CHEMISTRY OF REACH

- Stakeholder involvement (industry, including 3rd countries, NGO's (e.g. FoE, WWF, EEB, Greenpeace) throughout the whole co-decision process, including future review of the Annexes
- Publication of testing proposals on Agency website – all interested parties are invited to submit scientifically valid information (Art. 40(2))
- Authorisation – interested parties may comment before inclusion of substances in Annex XIV (Art. 58(4)) and may submit information on alternative substances or technologies for reviews of authorisations or for substances for which an application has been received (Art. 64(2))
- Restriction process – interested parties may comment on Annex XV dossiers (Art. 69(6))
- Management Board of the European Chemicals Agency includes also three non-voting members from interested parties
- Stakeholders can be invited by ECHA Committees (Risk Assessment and Socio-economic Analysis and Member States) and the Forum to attend meetings as observers and can be nominated as experts by the Member States

More Information

THE CHEMISTRY OF REACH

http://europa.eu.int/comm/environment/chemicals/index.htm

http://ec.europa.eu/echa/

http://europa.eu.int/comm/enterprise/chemicals/index.htm

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THE CHEMISTRY OF REACH

Current Events Analysis: Tracking the Progress of REACH Compliance

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Mamta Patel, Editor
Chemical Watch

CHEMICALWATCH
Briefing businesses on REACH and chemical risks

Chemical Watch
An Introduction

THE CHEMISTRY OF REACH

- **Came into operation May 2007 – one month before REACH came into force**
- **Independently owned**
- **Mission: to provide businesses with the information they need to manage the risks of chemicals in products responsibly**
- **Nominated for first European Parliament Prize for Journalism in 2008 for outstanding efforts to clarify a major EU issue.**
- **Has become the reference for news and views on REACH implementation and other chemical risk issues.**

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Perfluorinated chemicals join SAICM issues at last minute
18-May-09
NGOs concerned focus on emerging issues will detract from broader targets CW article

Chemical industry must do more on product safety
15-May-09
ICCM2 roundtable asks for more concrete actions from global industry, points to mismatch with SAICM goals
CW article

Other News

18 May: US review of formaldehyde expected "soon"

18 May: ACC launches online search facility for more than 1,000 chemicals

18 May: ICMM issues management strategy to 2020

18 May: Phosphorus-based flame retardants found in Arctic fauna

15 May: NGO report describes global activities to promote SAICM – and gaps in implementation

15 May: Polycarbonate bottles lead to "substantial increase" in urinary BPA levels

15 May: UK REACH competent authority publishes advice on REACH registration

15 May: UNEP welcomes ICCM2 outcome

14 May: ECHA must kick-start SIEF process, industry chief demands

Analysis and case studies: monthly briefing (April 2009)

Multiple challenges for American firms

UK sets out processes for prioritising SVHCs

Minerals consortia move to crystallise REACH SIEFs

Alloy makers manage uncertainty

Overhaul of biocides Directive anxiously awaited

UNEP mercury partnerships look to step up activities

Are REACH risks insurable?

Toxic assets – ethical investors seek warning of chemical risks

Stockholm Convention Parties to move beyond "dirty dozen"

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REACH in Practice: Background

THE CHEMISTRY OF REACH

- **2008 first year of implementation**
- **Efforts focused on:**
  - **finalising REACH technical guidance – OR surprise**
  - **finalising IUCLID 5 software to prepare data sets**
  - **preparing and testing REACH-IT (ECHA and industry)**
  - **registering legal entities in REACH-IT**
  - **making most of transitional period for PORDs (before June 2008)**
  - **working out system for obtaining REACH registration numbers for NONS chemicals**
  - **and, of course, pre-registration 1 Jun 2008-1 Dec 2008...**

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OR surprise at REACH pre-registration launch

'Only representatives' will have to register substances for each non-EU manufacturer

14-Apr-2008

'Only representatives' (ORs) appointed to register substances on behalf of non-EU manufacturers will have to submit separate registrations for each company they represent, the European Commission announced today.

Speaking at the joint Commission/European Chemicals Agency (ECHA) pre-registration launch event in Brussels, Otto Linher of DG Enterprise, said the change in interpretation followed a further round of dialogue with member states last week. He urged delegates to "spread the message as widely as possible".

During the meeting, the Commission conceded that it was wrong in its earlier interpretation, which required ORs to submit one registration aggregating tonnages for all the non-EU manufacturers it represents.

The news was welcomed at first sight by EU manufacturers at the meeting and ORs. The director of one OR company – REACH Only Representative – said "this brings clarity to the situation and is good news for everyone". But the consequences of the decision are still being worked out, Mr Linher stressed.

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Latest REACH-IT trials hit problems

Dramatic build up to pre-registration but contractors insist flaws can be ironed out in time

27-May-2008

With less than a week to go before REACH pre-registration begins on 1 June, final tests by industry and by the European Chemicals Agency (ECHA) have turned up significant problems.

Speaking last week after delivery of a production version of the system, ECHA executive director Geert Dancet said it looked much better but the Agency would carry out its own tests to be sure (*CW 19 May 2008*). Today, Mr Dancet revealed that "quite a lot of serious problems were identified in all different functions" during the internal tests which concluded on Friday.

The contractors charged with delivering the IT system – Trasys and TechniData – were informed of its findings. They are said to have expended "enormous resources" last week and over the weekend, resulting in a new version of the system complete with further test reports being delivered to ECHA last night.

The system is said to be much improved on earlier versions, but ECHA now plans to undertake its own further round of testing over the next two days. According to Mr Dancet, the contractors are confident of being able to address the problems in time and he is "optimistic by nature". A statement is expected

REACH in Practice: Pre-Registration

THE CHEMISTRY OF REACH

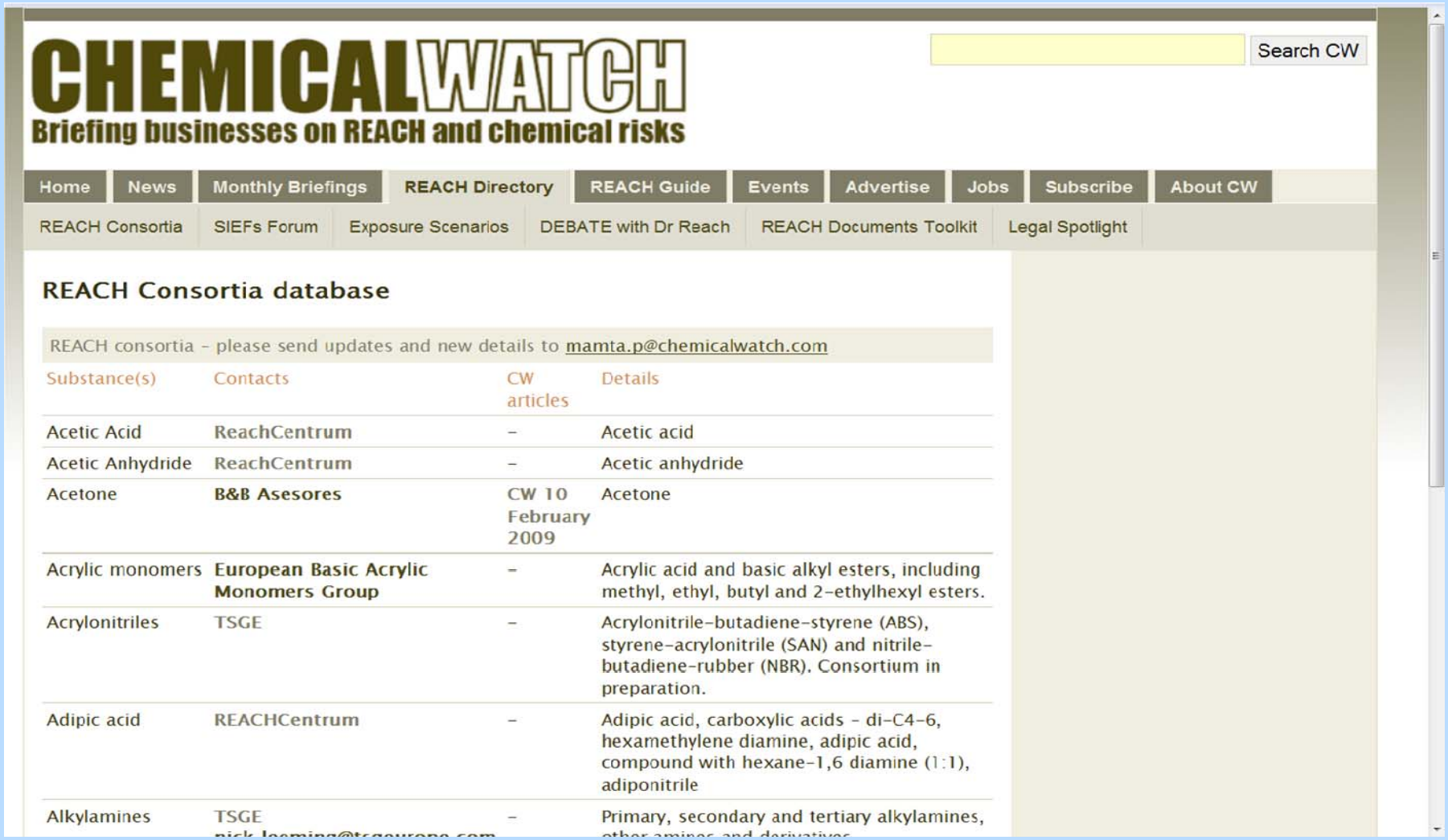
- Slow start – delay in ECHA introducing bulk submission facility caused many firms to wait;
- Summer holidays;
- High drama in the autumn with uncertainty all round about whether companies/ ECHA would cope;
- Last minute(?) double pre-registration controversy;
- Agency and company staff forced to work late nights, weekends to meet 1 December 2008 deadline;
- Eerie slowdown in last week or two;
- Then the shock at the scale of the task behind and ahead
- *- 2.7m pre-registrations (15x the expected number), 145,000 substances ≡ pre-SIEFs, 65,618 companies*
- Late pre-registration – 3,660 by 16 March 2009; not a flood but helpdesks, trade bodies report many firms 'confessing' to omissions.

REACH in Practice: Consortia

THE CHEMISTRY OF REACH

- Some established several years ago eg. aluminium
- Many set up over last two years in anticipation of REACH
- More than 100 REACH-specific consortia in operation, no official list
- Range from one substance eg. carbon black to tens of substances eg. LOA REACH Consortium for 170 lower olefins and aromatics
- Early issues over:
  - consortia legal agreements
  - fees (Mn consortium halved fees due to revised cost estimates)
  - transparency (http://chemicalwatch.com/REACH_consortia)
  - OR rights and obligations
  - membership basis – fairness for SMEs
- Shadow consortia have emerged in Japan to organise companies to optimise registration efficiency; how will they engage with parallel EU bodies eg. ethylene oxide and glycol? ECHA insists only one joint submission per SIEF.
- Alternative models, eg. CONCAWE licensing agreements, B&B Asesores joint submission groups

THE CHEMISTRY OF REACH



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REACH Consortia database

REACH consortia – please send updates and new details to mamta.p@chemicalwatch.com

Substance(s)	Contacts	CW articles	Details
Acetic Acid	ReachCentrum	–	Acetic acid
Acetic Anhydride	ReachCentrum	–	Acetic anhydride
Acetone	B&B Asesores	CW 10 February 2009	Acetone
Acrylic monomers	European Basic Acrylic Monomers Group	–	Acrylic acid and basic alkyl esters, including methyl, ethyl, butyl and 2-ethylhexyl esters.
Acrylonitriles	TSGE	–	Acrylonitrile-butadiene-styrene (ABS), styrene-acrylonitrile (SAN) and nitrile-butadiene-rubber (NBR). Consortium in preparation.
Adipic acid	REACHCentrum	–	Adipic acid, carboxylic acids - di-C4-6, hexamethylene diamine, adipic acid, compound with hexane-1,6 diamine (1:1), adiponitrile
Alkylamines	TSGE	–	Primary, secondary and tertiary alkylamines,

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Spanish group sets up new REACH consortia mechanism

Joint submission groups aim to offer companies a more resource-efficient route to registration

10-Feb-2009

Spanish consultancy B&B Asesores has established a number of consortia, which it has called European Joint Submission Groups, with the aim of offering an alternative, more resource-efficient route for the preparation of joint REACH registration dossiers. Substances covered so far include ethanol, acetone, oxalic acid, protein hydrolizates and others will be added in the future.

The company, which pre-registered a number of substances and intermediates and acts as an only representative, says the move is in response to demand from its clients who are concerned about the costs of some existing consortia and also do not have the resources to participate in consortia meetings.

B&B's Rosa Beaus, who coordinates the groups, says the consultancy will manage the preparation of a joint registration dossier without the need for company representatives to attend meetings. Participants will receive communication on the progress of the work and the compliance status in the language of their company. The approach should also be of interest to companies that do not use IUCLID 5 software as it will prepare registration dossiers in this format as required by ECHA.

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REACH in Practice: Pre/SIEFs

THE CHEMISTRY OF REACH

- Pre-registration presents enormous success or huge headache
- 2 pre-SIEFs > 5,000 members; 138 > 1,000 members; 88% < 25 members
- CEFIC surprised many with SIEF coding proposal but welcomed by ECHA
- ESCAPE plan to define best practice to relations between consortia and pre-SIEFs
- Dubious pre-SIEF members - even worse, posing as SIEF formation facilitators (SFFs)
- Vast majority of pre-SIEFs now have SFFs but unreliable indicator of activity
- ECHA asking lead registrants to make themselves known

REACH in Practice: Pre/SIEFs (cont'd)

THE CHEMISTRY OF REACH

- Scarily slow start to SIEF formation process – based on reports from industry, rate of lead registrants being notified to ECHA
- For 30 Nov 2010 deadline for high volume substances it is recommended that lead registrant dossiers are submitted by July 2010
- Industry demands for more guidance from ECHA
- ECHA says it's an industry responsibility – guidance from leading groups CEFIC, CONCAWE on SIEF operation, issues
- Those SIEFs that are making progress are those led by major producer or established consortia

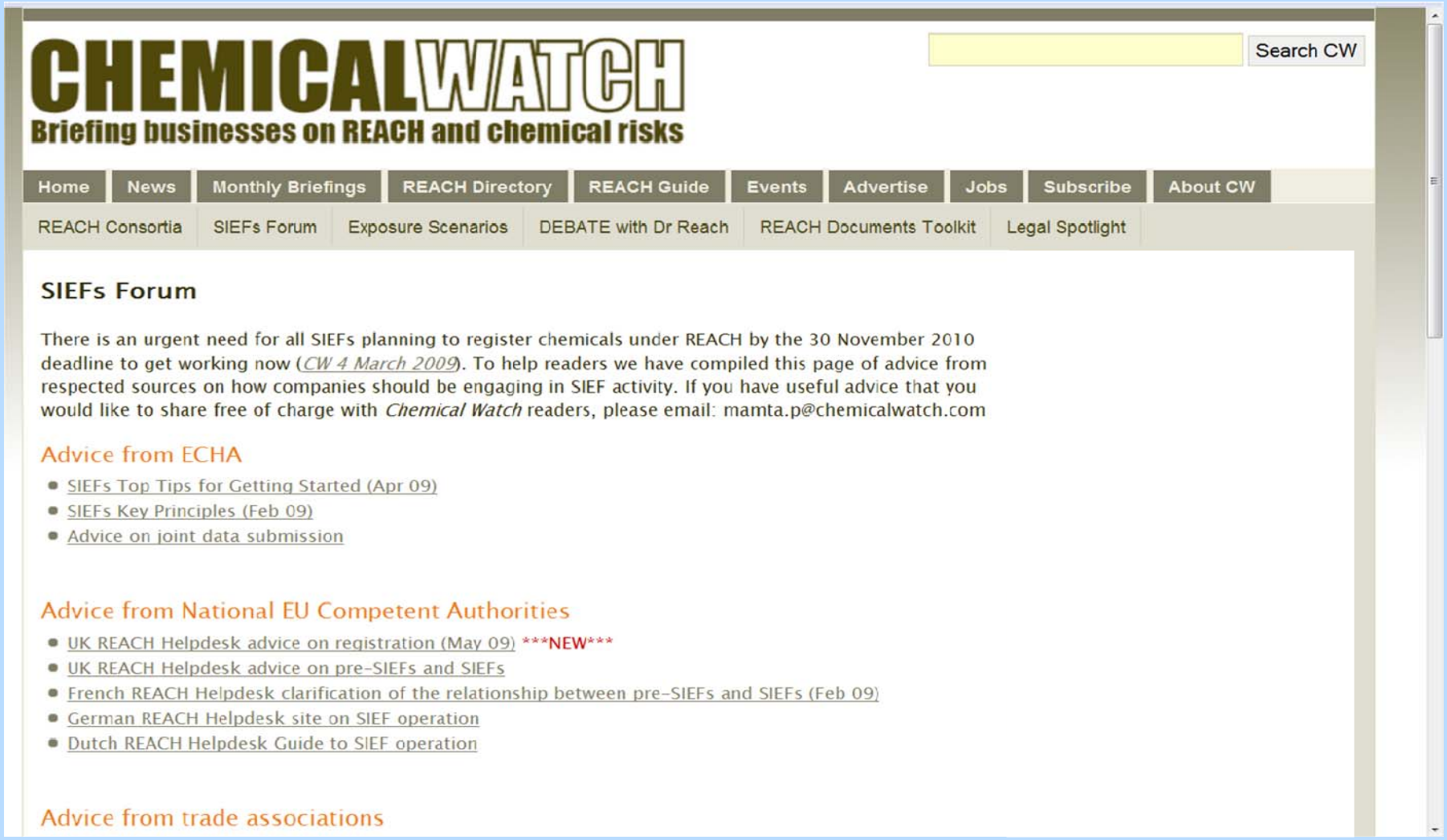
REACH in Practice: SIEF Issues

THE CHEMISTRY OF REACH

- How can a SIEF be formed if no pre-SIEF participant volunteers as SIEF formation facilitator (SFF)?
- How can a SIEF be formed if several pre-SIEF participants volunteer as SFFs?
- How can a SFF be replaced?
- Big companies have already formed consortia on a given substance. How can SMEs get involved in the same SIEF?
- How can two pre-SIEFs be merged to one SIEF?
- How can a pre-SIEF be split into two SIEFs?
- I have not heard anything from my pre-SIEF members. What should I do?
- Who can I contact if we have problems agreeing on our SIEF formation/management?
- How is the transition from a pre-SIEF to a SIEF made?

Reported to REACH Help-Net (EU REACH helpdesks network)

THE CHEMISTRY OF REACH



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SIEFs Forum

There is an urgent need for all SIEFs planning to register chemicals under REACH by the 30 November 2010 deadline to get working now (*CW 4 March 2009*). To help readers we have compiled this page of advice from respected sources on how companies should be engaging in SIEF activity. If you have useful advice that you would like to share free of charge with *Chemical Watch* readers, please email: mamta.p@chemicalwatch.com

Advice from ECHA

- SIEFs Top Tips for Getting Started (Apr 09)
- SIEFs Key Principles (Feb 09)
- Advice on joint data submission

Advice from National EU Competent Authorities

- UK REACH Helpdesk advice on registration (May 09) ***NEW***
- UK REACH Helpdesk advice on pre-SIEFs and SIEFs
- French REACH Helpdesk clarification of the relationship between pre-SIEFs and SIEFs (Feb 09)
- German REACH Helpdesk site on SIEF operation
- Dutch REACH Helpdesk Guide to SIEF operation

Advice from trade associations

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REACH in Practice: SVHCs

THE CHEMISTRY OF REACH

- First official candidate list of 15 substances of very high concern (SVHCs) announced by ECHA 28 October 2008, triggering Article 33 supply chain obligations
- First ECHA priority list proposal of 7 substances announced in January 2009 with sunset and application dates. Due to be finalised in June.
- ChemSec alternative Substitute It Now (SIN) List Version 1.0 announced Sept 2008
- ETUC alternative SVHC Priority List announced 31 March 2009
- Company declarable/restricted substance lists continue to be maintained.
- Recipe for confusion or welcome advance warning for supply chains?

REACH in Practice: Emerging Issues

THE CHEMISTRY OF REACH

- **Successful submission of registration dossiers – most currently failing at first hurdle due to unfamiliar electronic submission via REACH-IT. ECHA planning to issue checklist Q4 to help**
- **REACH registration number worry – how to include numbers on SDSs without enabling divulgence of CBI; solution due soon.**
- **Engaging the supply chain to prepare chemical safety reports – with exposure scenarios for hazardous substances; work underway in many fora, upstream and downstream user initiatives to be announced later this year**
- **Classification and labeling – for dangerous substances, must be agreed by SIEFs and notified to ECHA by 1 Dec 2010. NB: regardless of tonnage, whether due to be REACH registered or not**
- **Enforcement – how will this be carried out? who will be targeted? what will be the penalties? level playing field?**

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REACH in Practice: A Conclusion

THE CHEMISTRY OF REACH

- Economic recession – achieve more with less, rapid M&A, closure rate.
- Acceleration in global regulation – fuelled by REACH, SAICM, GHS eg. CCMP, TSCA reform
- Emerging issues – nanomaterials, complex science (effects may be neurodevelopmental, synergistic, transgenerational), growing consumer awareness, NGO activity, investor interest
- Supply chain pressures increase – product recall risks, globalisation, REACH communication requirements
- Corporate social responsibility agenda – pressure for greater disclosure of material risks, greater proactivity

THE CHEMISTRY OF REACH

An Industry Leader Speaks: Strategies for REACH Compliance

BDP INTERNATIONAL

Sharon A. Leyhow, Associate General Counsel
DuPont

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REACH

THE CHEMISTRY OF REACH

- **Chemical Company Challenges**
- **What are the next steps to achieve REACH Compliance?**
- **What's on the horizon?**

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Sharon A. Leyhow, Associate General Counsel
DuPont

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Why REACH?

THE CHEMISTRY OF REACH

Science-based	**Industry knows little about the majority of chemicals it uses and sells** • 86% of the High Production Volume Chemicals have less than the REACH-defined basic data sets •REACH requires full data from industry
Rule of Law	**Industry believes that safety is best handled through voluntary self-management** •Loss of public confidence in industry and governments led to REACH, a mandatory regulatory law •Burden of proof remains, but failure to ensure safe use means loss of market, civil and criminal penalties
Transparency	**Industry operates with significant restrictions imposed by competitive business information** •REACH requires the sharing of use information with suppliers/customers and testing data between competitors •Much of the hazard, exposure and risk data may be available to anyone globally.

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REACH

THE CHEMISTRY OF REACH

REACH differs from other regulatory systems in important ways:

- **Applies to substances not products**
  - Companies deal with products (e.g. end-uses/markets, volumes, product stewardship)
  - Substances ≠ Products. Corporate data and planning may not align with regulatory requirements
- **"Safe use" rests entirely on Chemical Industry**
  - Regulatory authorities do not approve a corporation's declarations at any stage
  - Corporations are required to set standards which are binding and easily enforced
  - Most information submitted may be publically available around the globe
- **Companies are required to work with and depend on others**
  - Submission done by a lead registrant on behalf of all who register a substance
  - Certain data are required to be exchanged with competitors and others through SIEFs
  - Use information must be shared among supplier and customers
- **REACH will affect:**
  - Every time chemical company uses substances
  - With every delivery of chemical products
  - Inside and outside the EU through the supply chains

What is REACH?

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- **A licensing system for access to the EU market**
  - All substances imported or manufactured
  - Pre-registration is a temporary license
  - Registration is a license which can be restricted or revoked
- **Registration is required before market access**
  - Takes time – up to a year
  - Can be costly -- € 500 to € 1.000.000
  - Requires data, risk assessment and safe-use definition
- **Not an event, but a on-going process requiring continued investment of resources**
  - 10 year full implementation (2008 – 2018)
  - Requires proof of compliance with enforcement by EU member states
  - Documentation, tracking and updates are mandatory
  - Impacts nearly every major business process
  - Includes changes to classification, labeling and ESDS

What is REACH?

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No data, no market

All activities impacted

Liability

Global impact

to the EU market

All substances imported or manuf

Pre-re

market access

Takes time – up to a year

Can be costl

Not an ev

continued investment

of resources

10 year full implementation (2008-

Requires proof of compli

process

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REACH

THE CHEMISTRY OF REACH

- **What are the next steps to achieve REACH Compliance?**

REACH: Goal is Registration

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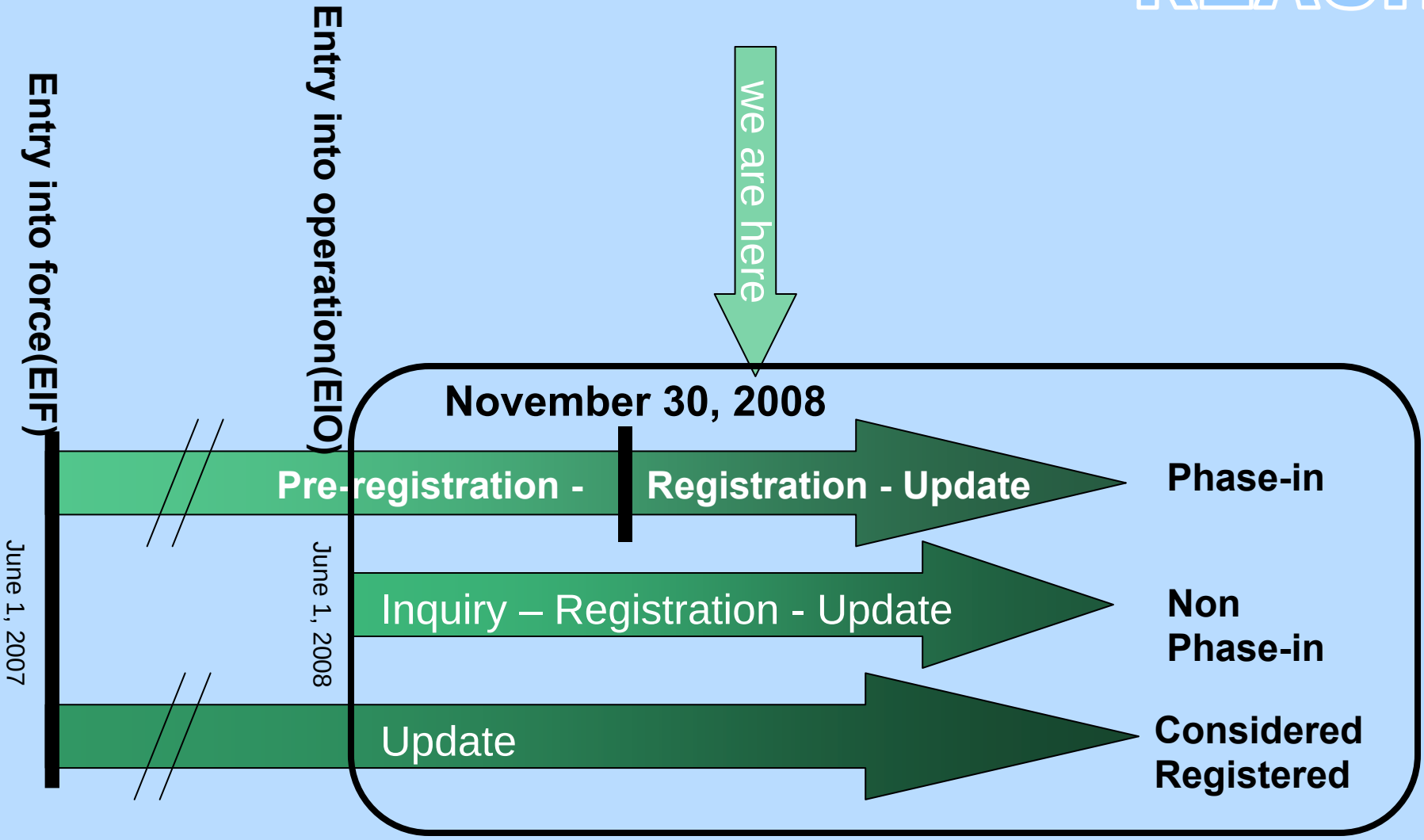

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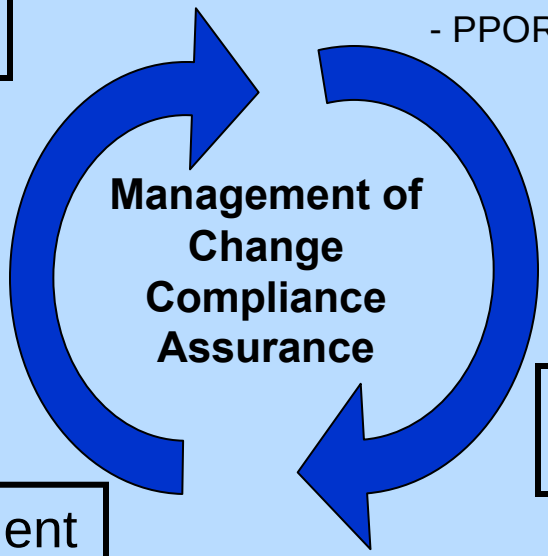
Registration Processes



Dossier Submission

Starting Points
- Pre-registration
- Inquiry
-ELINCS notification
- PPORD

Contact person & address
EINECs/ELINCs/CAS #
Intermediates
No Longer Polymers
Tonnage band
Date of submission

Consistency check
Final approval prior to submission
QA/QC

Dossier Review

Contact person & address
EINECs/CAS #/Subst. names
Tonnage band
Substance ID
Process Description
CBI
IUCLID
QA/QC
Site
Legal entity
New OR
% own use
SDS

Regulatory & CB information

Preliminary Risk Assessment

Available hazard data
Preliminary DNEL & PNEC
Prel. Use
Operational conditions
Risk Mgt Measures

Registration & CBI Strategy

Initial Subst. ID
Intermediate/PPORD exemption/Strict control
Only Rep.
Import LE
Tonnage band
Lead role in SIEF & submission

Risk Assessment refinement & Exposure Scenario completion

Use assessment
Exposure scenario determination
Operational conditions
Uses advised against
Risk mgt measures
CSR
IUCLID
Operations compliance
QA/QC

Hazard Assessment

End-point summary
PNECs/DNELs
PBT/vPvB Assess't
Ranges
Safety factors
Argumentation
QA/QC

Use information

All downstream uses
Uses advised against
Current risk mgt measures

SIEF & Joint Submission
Data Compilation

Classification
Alone (no SIEF), joint, lead

Substance sameness
Data needs
Data gap completion
Testing Strategies

Robust Study Summaries
Read-across
IUCLID
QA/QC

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Flow for phase-in substances

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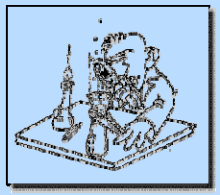
Production or Import

↓

Analysis and identification



↓

Pre-registration

↓

SIEF

↓

Data sharing & data assessment

↓

Lead & Joint submission

↓

Other submissions

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SIEF - Substance Information Exchange Forum

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- **Required membership**
  - **No formal process to identify initial members**
  - **9.5- year duration**
- **Aim:**
  - **Exchange of information**
    - ***data sharing (voluntary & required)***
    - ***testing proposals***
  - **Agree Classification & Labeling**
- **Data points:**
  - **New data (tox) made available**
  - **Revision of Classification**
  - **Testing proposal preparation**
  - **Discussion on safe use (risk management measures, operational conditions, etc.)**

Joint submission of data by multiple registrants

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- Joint submission
  - One Substance “One Registration”
- Process
  - The Joint submission members choose a lead registrant
  - The lead submits a complete data package first
    - *The agreed data package (studies etc.)*
    - *Company specific information (compositional details of the substance etc.)*
  - The members submit only their specific information
- Note: The data holders are part of the SIEF, but they have no role in the Joint Submission. The data holders will in most common cases also not be part of the consortium.

Own Submission

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Information requirement (Article 10)	Lead registrant		Member
	Lead registrant own submission	On behalf of the joint submission	
a (i) the identity of the manufacturer(s) or importer(s)	✓	☒	✓
a (ii) the identity of the substance	✓	☒	✓
a (iii) information on the manufacture and use(s)	✓	☒	✓
a (x) exposure information (1 to 10 tonnes)	✓	☒	✓

✓ = submits ☒ = does not submit ✱ = optional

Joint Submission

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Information requirement (Article 10)	Lead registrant		Member
	Lead registrant own submission	On behalf of the joint submission	
a (i) the identity of the manufacturer(s) or importer(s)	✓	☒	✓
a (ii) the identity of the substance	✓	☒	✓
a (iii) information on the manufacture and use(s)	✓	☒	✓
a (iv) the classification and labelling	☒	✓	☒
a (V) guidance on safe use	✱	✱	✱
a (vi) study summaries Annexes VII to Xi	☒	✓	☒
a (vii) robust study summaries Annexes VII to XI	☒	✓	☒
a (ix) proposals for testing where listed in Annexes IX and X;	☒	✓	☒
a (x) exposure information (1 to 10 tonnes)	✓	☒	✓
(b) chemical safety report	✱	✱	✱

✓ = submits ☒ = does not submit ✱ = optional

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REACH

THE CHEMISTRY OF REACH

- **Science-based Policies and Programs**
- **Adherence to the Rule of Law**
- **Overwhelming Transparency**

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What's on the horizon?

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- **TSCA Reauthorization**
- **Managing Global Harmonization System**

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On the Enforcement Horizon: What Are Your Risks?

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Introduction to REACH enforcement

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- **REACH requires each EC member state to appoint a competent authority and maintain an adequate enforcement system**
- **Member states had to have their enforcement regimes in place by 1 December 2008**
- **Enforcement regimes must provide for "effective, proportionate and dissuasive" penalties for non compliance**
- **Results of enforcement must be reported by member states to the European Commission every 5 years**

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The Forum

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- **Coordination and cooperation of competent authorities across the EU in relation to enforcement will be vital**
- **REACH encourages cooperation and coordination between member states' competent authorities via a Forum for exchange of information on enforcement**
- **On 30 April 2009, the ECHA announced that the first coordinated REACH enforcement program had started through the Forum**
- **Inspections will be made across the EU to check that manufacturers and importers have made the necessary registration/pre-registration**

The UK example

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- **Reach Enforcement Regulations 2008 came into force on 1 December 2008**
- **In the UK, the Health & Safety Executive is the primary national enforcing authority**
- **It has already dealt with 60 non compliance issues since December 2008**
- **Although the HSE is the primary enforcing authority, a number of other bodies are also involved**

The UK example

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- **HSE will enforce REACH registration requirements and duties**
- **HSE will enforce REACH supply chain-related duties up to the point of retail sale**
- **Local authority trading standards will enforce REACH supply chain obligations at the point of retail sale**
- **Environment Agency, HSE and local authorities enforce REACH use-related duties**
- **The above entities will be supported by HM Revenue and Customs who will detain goods at import**

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The UK example

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- **UK enforcing authorities have full powers of investigation**
- **They may enter premises, search them, detain goods, take samples, test, question staff, etc**
- **HM Revenue & Customs can detain a substance or article that has been imported for up to 2 days.**
  - **This gives the enforcement authorities time to arrive on site and make an assessment**

The UK example

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- **Failure to comply with:**
  - **Registration requirements**
  - **Supply chain requirements**
  - **End use requirements**

  is a criminal offense

- **Fines and imprisonment**
- **Possible liability for directors and officers**
- **If enforcing bodies do not think that a criminal punishment is sufficient, it can also make a civil claim for, for example, profits made from the sale of non-compliant articles/substances**

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THE CHEMISTRY OF REACH

Questions & Answers

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CHEMICALWATCH
Briefing businesses on REACH and chemical risks

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