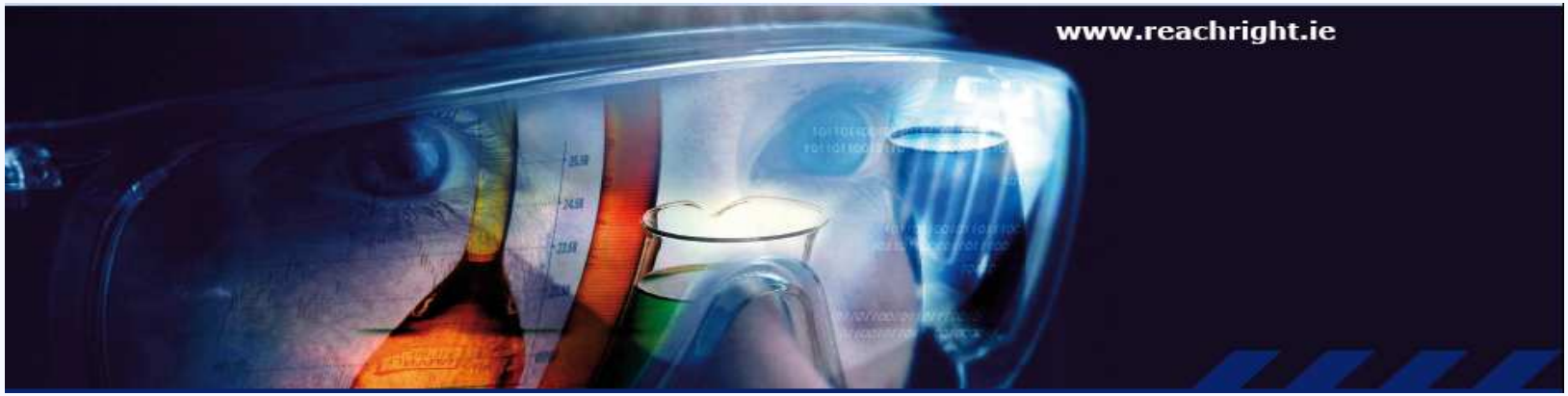
REACH Update
OHSI Annual Conference
19th February 2009



Roseleen Murphy
Health & Safety Authority

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Overview

- Introduction
- Registration
- Pre-registration
- Downstream Users & Information in the Supply Chain
  - The Safety Data Sheet
  - Exposure Scenarios
- Authorisation/Candidate List

Key Elements

- **Registration** of all substances Manufactured/Imported ≥ 1 tonne/yr
- **Evaluation** of some substances
- **Authorisation** only for some substances of very high concern
- **Restrictions** - the safety net (Community wide action)
- **Information in the Supply Chain-** applies to all

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1. Registration

- Responsibility for management of risks with Manufacturer/Importer (M/I)

- Registration requires M/I to:
  - Generate data on substances
  - Use data to assess risks
  - Develop risk management measures

Scope of Registration

Generally, substance on its own or in a preparation, or incorporated into an article, manufactured in, or imported into, the EU, at quantities greater than 1 tonne per annum, must be registered

Who has to register?

- Only a legal person established in EU can register
- Registration applies to:
  - EU **manufacturers and importers of substances**, on their own/in preparations
  - EU **producers/importers of articles**
  - EU-based '**only representatives**'
- Within these groups, each legal entity must register

Registration – a phased process

- Non phase-in substances
  - Registration required before M/I can take place
- Phase-in substances
  - Substance listed on EINECS or
  - Manufactured in EU but not placed on EU market 15 years before REACH or
  - No-longer polymer

2. Pre-registration

- Pre-registration from Jun – Dec 2008
- Applied to 'phase-in' or existing substances
- Allows Potential Registrants extended registration deadlines
- Facilitates the formation of Substance Information Exchange Forums (SIEFs)
- Completed via the online system

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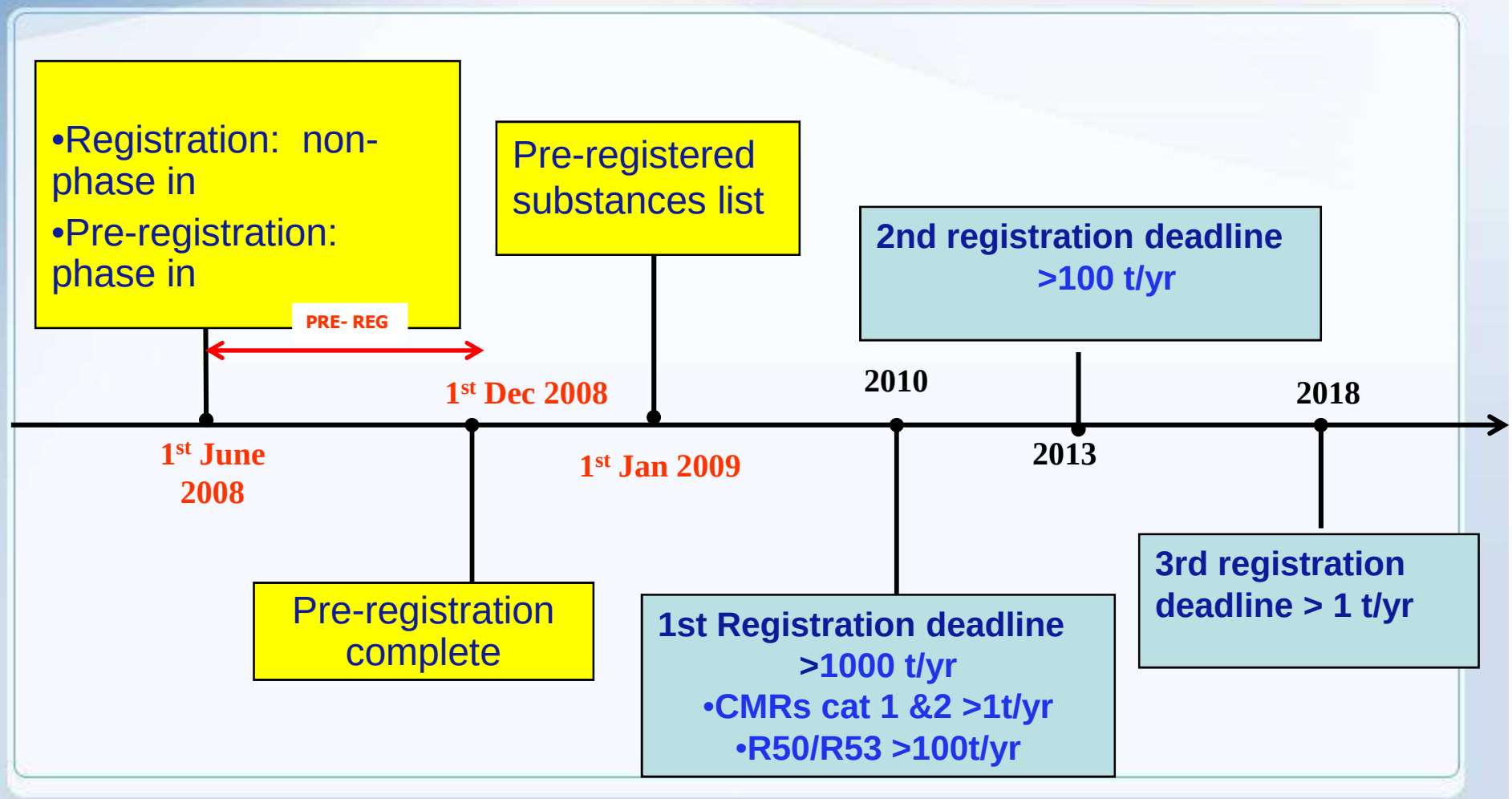
Registration Timetable



Pre-Registration Stats

- 2.75m Pre-registrations (estimate was 150,000)
- 150,000 different substances
- 65,000 companies signed up in REACH IT
- Pre-registration list published by ECHA

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After Pre-registration

- Pre-registrants of the same substance organised into SIEFs
- Data gathering and data sharing process begins
- Preparation of Registration Dossier and Chemical Safety Report(where applicable)
- First time M/I can pre-register after 1st Dec

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3. Downstream Users

- ‘A natural or legal person established in the Community who uses a substance, on its own or in a preparation, in the course of his industrial or professional activities’
- A Distributor or Consumer is not a Downstream User

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Downstream Users after Pre-registration

- DU should check that Supplier has pre-registered or registered the substance
- List of pre-registered substances on the ECHA website
- If substance is not on the list DU can notify ECHA of their interest online

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Information in the Supply Chain

- REACH introduces increased requirements for information supply
- 2-way communication
  - DU to Supplier
  - Supplier to DU
- DU should communicate their use to suppliers

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Information in the Supply Chain (2)

- DU obligations triggered upon receipt of Information from Supplier
  - Safety Data Sheets
  - Exposure Scenarios

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The Safety Data Sheet

- Primary tool for downstream communication
- Hazards, risks and Control Measures
- Improve information on substances in SDS
- Slight change in format
- Exposure Scenarios may be attached

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Exposure Scenario

- Describes conditions under which a substance can be used safely
- Responsibility for the Registrant of the substance to prepare the ES
- Will be attached to the SDS where and when appropriate

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Exposure Scenario for Cleaning Product

Description of process	**Cleaning agent** **Dispensed using trigger spray**
Operating conditions	**User cleans using spray once per day for average duration of 10 minutes at room temperature each day of the Year.** **Conc. Of classified substances: Formulation contains up to 8% surfactant, 0.1 % solvent and 10% fragrance**
Recommended RMM	**Occupational: No RMM required to control inhalation/dermal exposure** **Consumer: Wash & dry hands after use, Keep out of reach of children** **Environment: Discharge cleaning water into sewer** **Waste: No RMM required**
Prediction of exposure **IS DU operating within the conditions set in ES**	**Worker, consumer and environmental exposure** **Worker, consumer (do not use more than 500g per day), environment**

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When I receive an SDS/ES what do I do?

- Check that your use is covered
- Identify the Risk Management Measures (RMM)
- Compare the RMM with your current RMM and conditions of use
- Identify any gaps update relevant documentation
- Implement RMM

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What happens if my use is not covered in ES?

- Options:
  - Make use known to supplier
  - Change conditions of use
  - Source another supplier whose ES covers own use
  - Source alternative substance
  - Prepare own targeted CSR

4. Authorisation

- System for granting an authorisation for certain uses of certain substances
- Applies to substances identified as Substances of Very High Concern(SVHC)
  - CMRs, PBTs and vPvB
- Substances identified as SVHCs are included on the candidate list, published by ECHA

Candidate list

- First Candidate list published 28th Oct (15 substances of very high concern)
- New legal obligations for communication in the supply chain
- Provision of SDS and for article suppliers
- ECHA prioritised 7 substances for inclusion in Annex XIV (substances subject to authorisation)

Do you use these substances?

- **5-tert-butyl-2,4,6-trinitro-m-xylene(musk xylene)**
- **Alkanes, C10-13, chloro (short chain chlorinated paraffins; SCCPs)**
- **Hexambromocyclododecane(HBCDD) and all major diastereoisomers identified**
- **4,4'-Diamino diphenyl methane (MDA)**
- **Bis (2-ethylhexyl) phthalate (DEHP)**
- **Benzyl butyl phthalate (BHP)**
- **Dibutyl phthalate (DBP)**
- If so your use may be subject to Authorisation

Public Consultation

- Interested parties are invited to submit comments on the proposal
- On the inclusion onto Annex XIV
- On the uses that should not be subject to Authorisation
- Public consultation until 14th April
- Recommendation for Annex XIV to COM by ECHA, 1st June 2009
- www.echa.eu

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Guidance and support available

- Technical Guidance Documents
- www.echa.eu

- REACH Helpdesk
  - www.reachright.ie
  - 1890 289 389
  - reachright@hsa.ie
  - REACH/CLP E-Bulletin

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