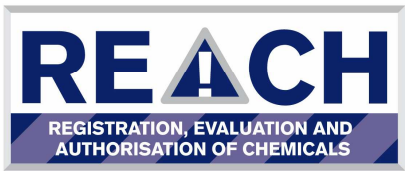
Welcome!

Get Ready for REACH
Information Seminar

HEALTH AND SAFETY AUTHORITY

REACH
REGISTRATION, EVALUATION AND AUTHORISATION OF CHEMICALS

REACH Regulation- An Overview



Outline

- Scope
- Exemptions
- Identifying your Role
- Other Roles under REACH

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What is REACH?

- REACH is a European Regulation for the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals
- One coherent system for all chemicals in the European Union (EU)
- REACH places greater responsibility on industry to manage the risks that chemicals may pose to human health and the environment
- In principle REACH applies to all chemicals

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Objectives

- Protection of Human Health & the Environment
- Maintain a competitive and innovative EU chemicals industry
- Free circulation of substances on the EU market

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Key Elements

- **Registration** of all substances ≥ 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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Scope of REACH

Chemicals:

-Substances on their own

-Substances in preparations

-Substances in articles.

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Full Exemption from REACH

- Radioactive Substances
- Substances transported or under customs supervision
- Waste as defined in Directive 2006/12/EC
- Substance used exclusively as a non-isolated intermediate
- The carriage of dangerous substances and dangerous substances in dangerous preparations by rail, road, inland waterway, sea or air

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Specific exemptions

Titles II, V, VI and VII of the Regulation do not apply if substance:

- **Used in medicinal products for human or veterinary use**
- **Used in food or feeding stuff**

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Specific exemptions

Title IV of the Regulation does not apply to preparations in final state:

- Medicinal products for human or veterinary use
- Cosmetic products
- Medical devices
- Food or feeding stuffs

…..other specific exemptions in Article 2, Annexes IV and V, Polymers

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Scope contd.

- **Manufacture**
- **Import**
- **Use**

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Identifying your Role

- **Manufacturer** -EU producer of substances
- **Importer** –Imports substances from non-EU countries
- **Downstream User-** Professional or industrial users
- **Distributor**- Stores and places on Market
- **EU Only Representative-** Takes on role of Importer

You may have more than one role!

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Identifying your Role

EU MANUFACTURER

2 CHEMICALS

GERMANY

NON EU MANUFACTURER

1 CHEMICAL

JAPAN

Downstream user

Importer

Importer

PAINT FORMULATOR

IRELAND

Only Representative

EU Based

Downstream user

CLEANING SOLUTION

EU DISTRIBUTOR

Downstream user

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Chemical company

- Chemical company manufacturers a chemical substance (sodium chloride) in France

Role

Manufacturer of Substance

- Purchase process cleaning substance from distributor in Denmark

Role

Downstream user

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Roles under REACH

- **Member State Competent Authorities-** Health & Safety Authority, Ireland
- **European Chemicals Agency-** ECHA-Helsinki
- **European Commission-** Brussels
- **NGO's & 3rd Parties**

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Conclusion

- Greater responsibility on industry
- Substance based
- Exemptions
- Determine your role for each substance

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REACH – Pre-Registration and Registration

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Outline

- Registration
  - Aim
  - Scope
  - Procedure
- Pre-registration
  - Procedure
  - Timelines
- Joint submissions
- SIEF formation
- Duty to inquire

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Aim of 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

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Scope of Registration

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

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Registration of Substances

- General obligation on M/I to register substance at > 1 t/yr
- Submit dossier to ECHA via REACH-IT
- Info requirements increase with tonnage
- No data no market rule of registration
- Framework to demonstrate adequate control

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Registration of substances – special cases

- Substances regarded as registered:
  - Notified in accordance with Directive 67/548
  - Active substances used in plant protection and biocidal products
- Reduced registration for:
  - On-site isolated intermediates >1 t/yr
  - Transported isolated intermediates > 1 t/yr
- PPORDs

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Substances in Preparations

- Substances in preparations (M/I > 1 tonne per yr) are subject to registration
- Need to know % content of each substance in preparation
- Calculate overall tonnage

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Substances in Articles

Article

an object, which during production, is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition

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Substances in Articles

- **Registration (Article 7.1)**
  - Present in article > 1 t/yr and
  - Intended to be released

- **Notification (Article 7.2)**
  - Substance of very high concern>1t.yr and
  - > 0.1% w/w

  - Does not apply to substances already registered for that use

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Who has to register?

- Only a legal person established in EU can be a registrant

- 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

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Registration – the Process

- Registration dossier submitted electronically to ECHA

- Two main components:

(i) a technical dossier, required for all registered substances

(ii) a chemical safety report, required at > 10 tonnes per year

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The Registration Dossier

- Information includes:
  - Identity of M/I and the substance
  - Information on manufacture and use
  - C&L
  - Guidance on safe use
  - Study summaries
  - Proposals for further testing
- Information requirements set out in Annexes VI to XI

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Common Points

- ECHA assigns submission number to all registrations; undertakes completion check
- Once registration complete, ECHA assigns registration number and date; no formal approval
- Registrant can manufacture or import unless hears otherwise from ECHA
- Registrant must update registration with new information

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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 the EU, but not placed on market, at least once in the 15 years before entry into force of REACH; or
  - ➢ No-longer polymer

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Pre-Registration

- Phase-in substances
- 1 Jun 2008 – 1 Dec 2008
- Potential registrants send info (to ECHA, via REACH-IT) on:
  - Identity of substance and registrant
  - Envisaged deadline for registration
- ECHA to publish list (1st January 2009)

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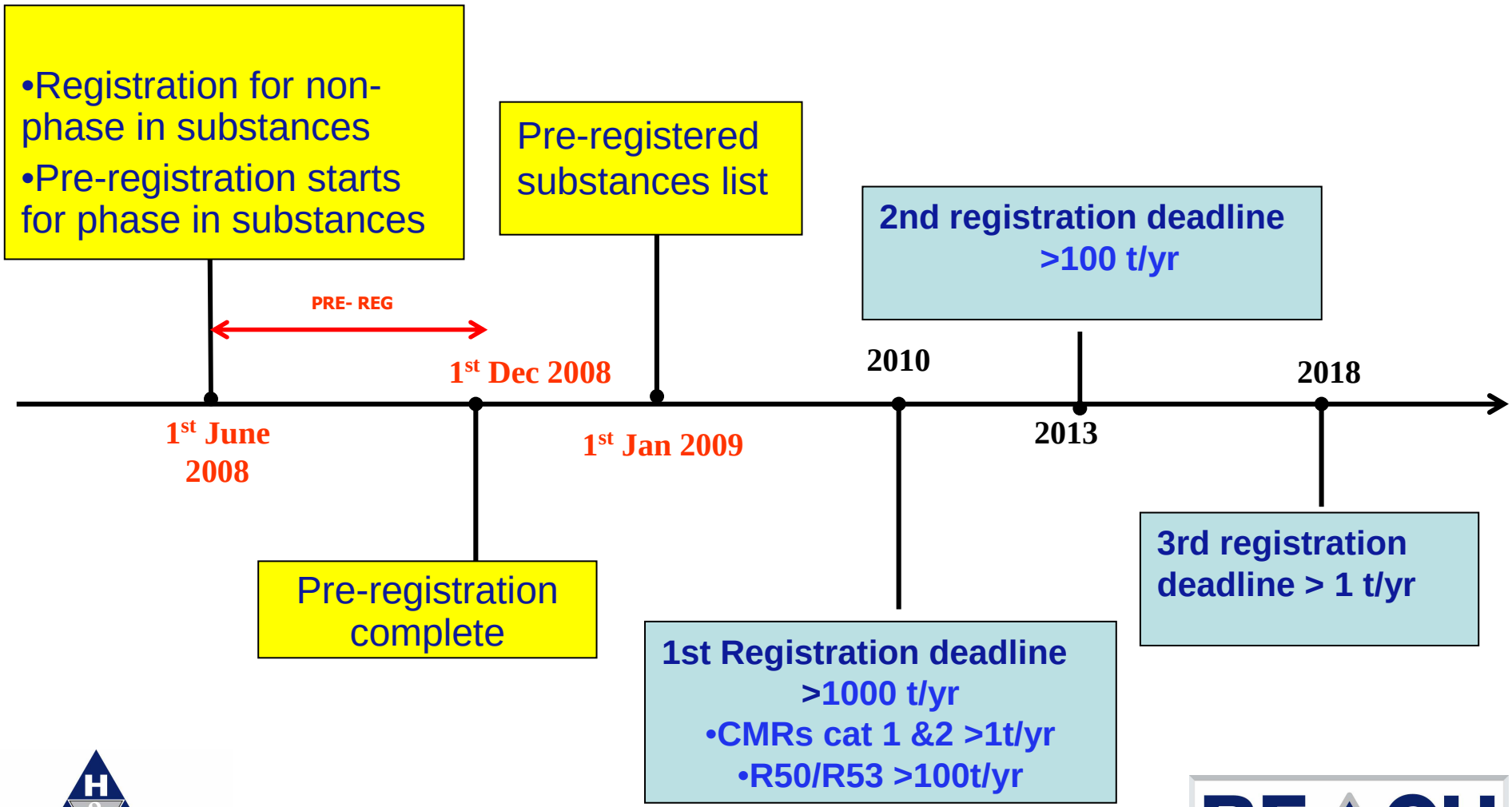
Registration Timetable



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Pre-Registration

- Opportunity not to be missed!
- Advantages:
  - Facilitates data sharing
  - Reduced testing on vertebrate animals
  - Reduced cost
  - Allows industry to continue to M/I until relevant deadline
- Consequence of not pre-registering: immediate registration

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Joint Submissions

- Mandatory:
  - Hazardous properties, incl. studies
  - C&L
  - Testing proposal
- Optional:
  - CSR
  - Guidance on safe use
- Separate submission
- Opt out

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Substance Information Exchange Forum (SIEF)

- SIEF formed for each pre-registered substance, with same chemical identity
- Members can be potential registrants and data holders
- Facilitates data sharing
- Agree on generation of new test data
- Agree on C&L of the substance

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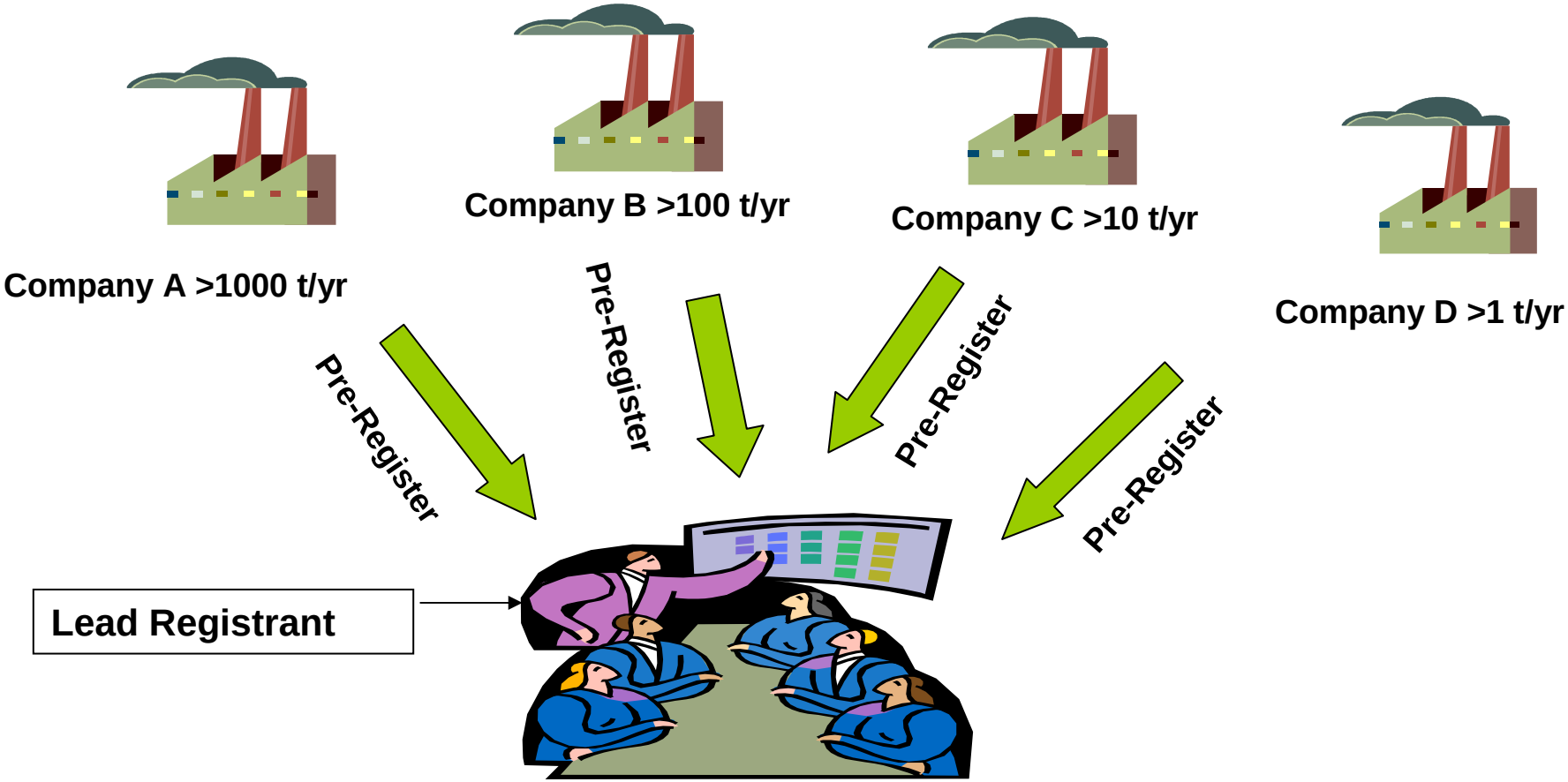
PHASE IN SUBSTANCE



Substance Information Exchange Forum (SIEF)

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Inquiry before Registration

- Applies to non phase-ins and phase-ins not pre-registered
- Registrant must inquire to ECHA of any previous registration
- ECHA informs registrant of status and how to proceed

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Key Points

- Registration applies to substances
  - manufactured in, or imported into, the EU at
  - >1 tonne/yr
- Each manufacturer or importer must register
- Pre-registration: opportunity
- 1st June 2008 – 1st December 2008

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Communication in the Supply Chain

Health and Safety Authority

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Communication in the Supply Chain

- Critical to success of REACH
- Greater communication than in past
- Pro-active communication benefits all
- Start now!!

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Communication Tools used by Registrants

- ***Chemical Safety Assessment (CSA)*** **determines** the necessary operating conditions and risk management measures to ensure **adequate control** of risks

- ***Chemical Safety Report (CSR)*** **documents** the outcome of CSA

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Tools for Communicating *Down* the Supply Chain

- ***Safety Data Sheet (SDS)***
  communicates hazards/risks downstream

- ***Exposure Scenario (ES)***
  communicates use and risk management conditions downstream to allow adequate control

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The Chemical Safety Assessment (CSA)

Registrant must

- Compile CSA at > 10t/yr
- Ensure risks are adequately controlled
- Estimate exposure for manufacture and/or each identified use
- Specify risk management measures (RMM) for each use
- Address use identified by DU

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What must an Exposure Scenario cover?

- Manufacture (EU)
- Manufacturer / importers own use
- Identified downstream use (s)

- Entire life cycle
- Exposure of workers, consumers, environment, man via environment
- Specific  Generic

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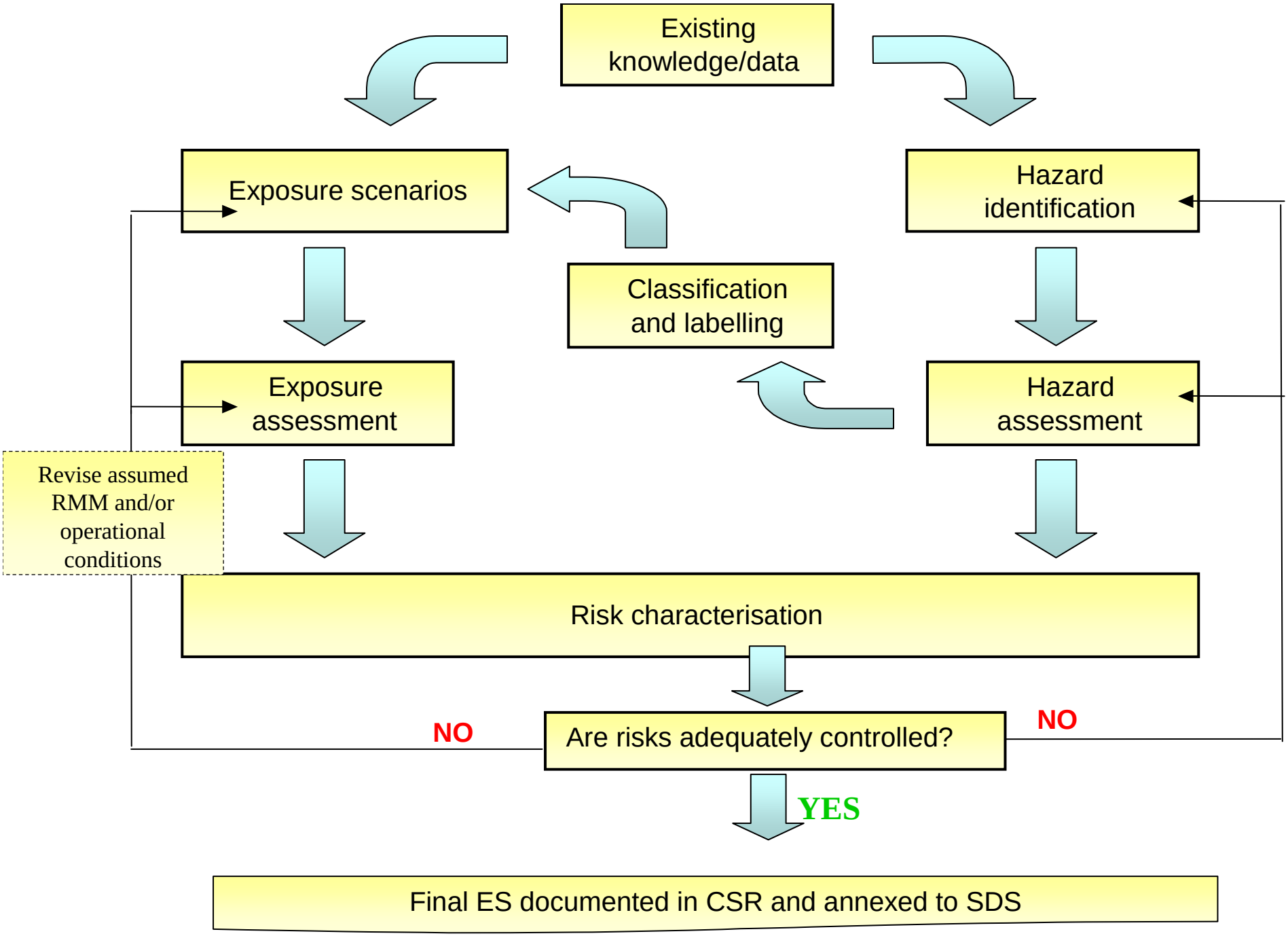
Existing knowledge/data
Exposure scenarios
Hazard identification
Classification and labelling
Exposure assessment
Hazard assessment
Revise assumed RMM and/or operational conditions
Risk characterisation
NO
Are risks adequately controlled?
NO
YES
Final ES documented in CSR and annexed to SDS

Exposure Scenario for Cleaning Product

Description of process	**Cleaning agent for hard surfaces in kitchen** **Dispensed using trigger spray**
Operating conditions	**Consumer cleans kitchen surface using spray once per day for average duration of 10 minutes.**
Product specification	**Formulation contains up to 8% surfactant, 0.1 % solvent and 10% fragrance**
Recommended RMM	**Human Health:** **No RMM required to control inhalation/dermal exposure** **Keep out of reach of children** **Wash & dry hands after use** **Environment:** **No RMM required.**
Status and date of ES	**Final based on demonstration of adequate control** **May 2007**

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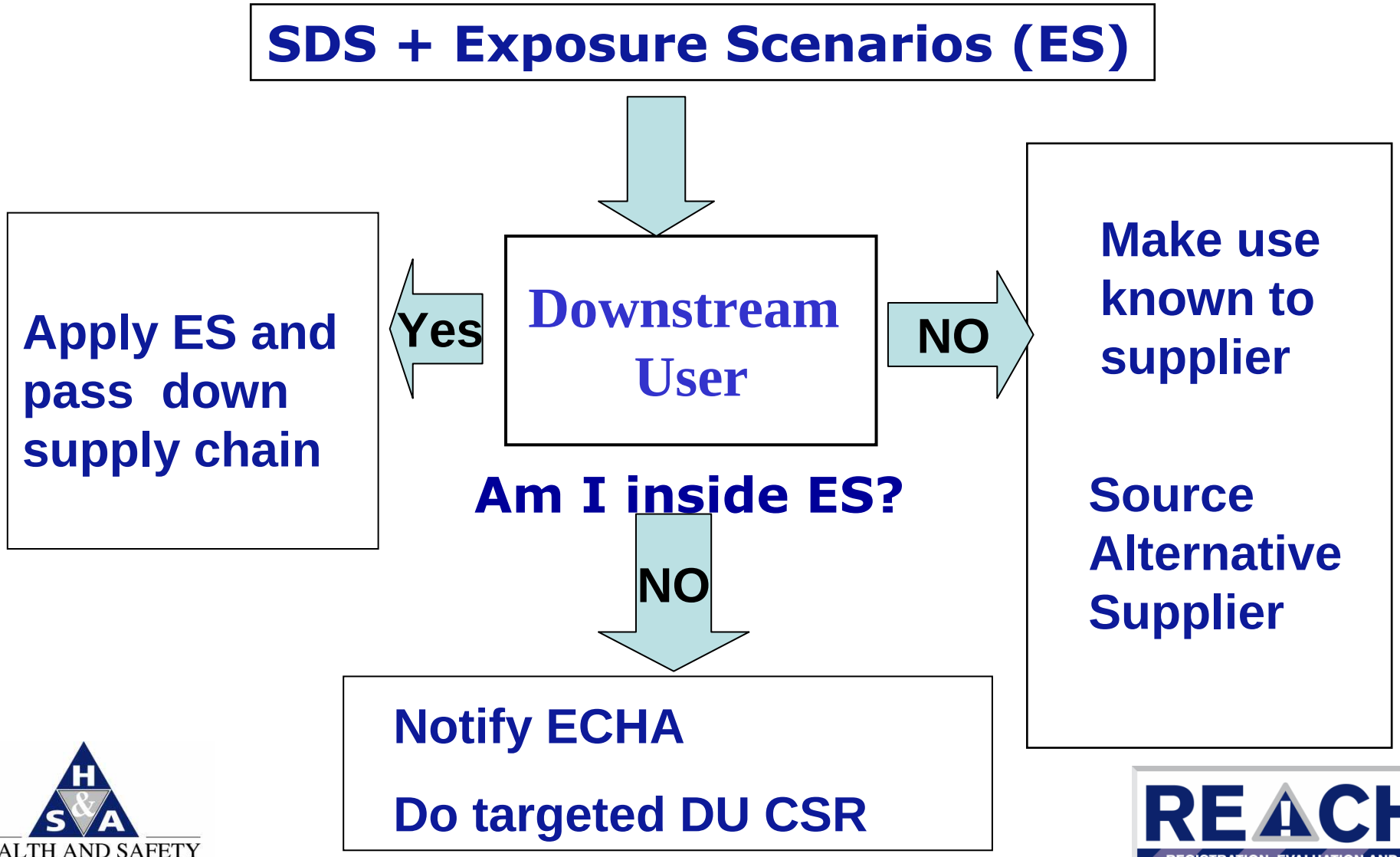
Downstream User – Am I covered by my suppliers SDS?



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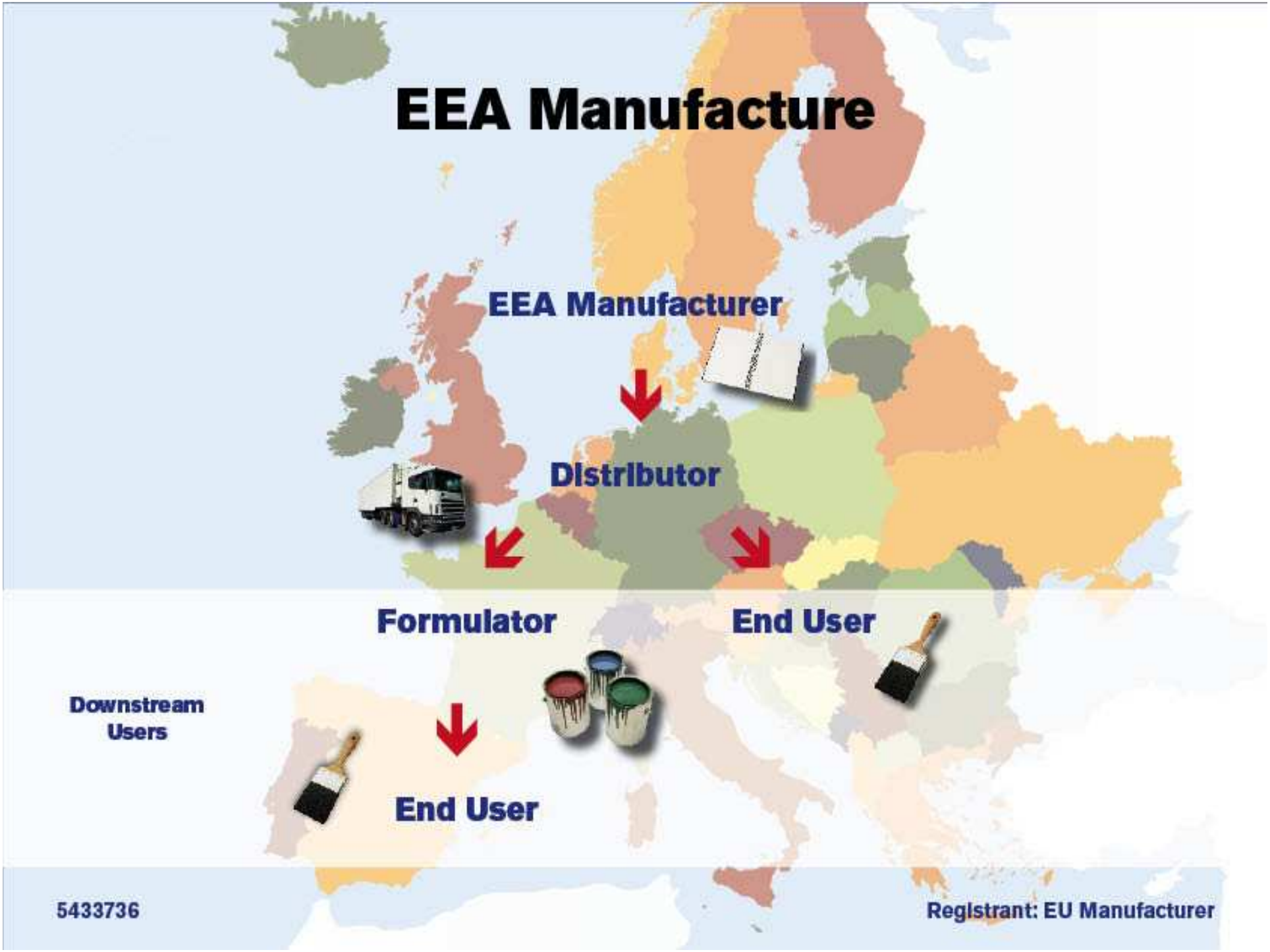
EEA Manufacture



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Registrant: EU Manufacturer

Rights of Downstream Users

- Make use known to manufacturer/importer
- Carry out own Chemical Safety Assessment
- Participate in Substance Information Exchange Forum (SIEF)

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The Safety Data Sheet

- Primary tool for downstream communication
- Slight change in format
- ES should be attached for substances & preparations at > 10 t/a and classified as dangerous
- Now required for PBTs/vPvBs and substances of 'equivalent concern'
- When do new requirements apply?

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Additional Communication Requirements

- Communication of information where no SDS required
- Communication about 'high concern' substances in articles
- Communication about risk management

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Start Communicating Now!

- Identify the substances and preparations you use
- Prepare an inventory
- Determine your role
- Prioritise those that are most important or likely to be impacted by REACH
- Contact your suppliers and customers

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Industry Support & Guidance

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Guidance –Who can help?

- HSA - Competent Authority
  - Helpdesk
  - Web site
  - Communications campaign
- European Chemicals Agency (ECHA), based in Helsinki
  - Central point of contact
  - Technical guidance
- Industry Groups e.g REACHAid (IBEC)

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Health & Safety Authority Role

- Competent Authority
- Helpdesk
- Enforcement Role
- Substance Evaluation
- ECHA committees

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Authority Helpdesk

- Website:www.reachright.ie
- FAQs
- Contact us:
  - Lo-call: 1890 289 389
  - Email: reachright@hsa.ie
- Scope of Helpdesk

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Network of MS Helpdesks

- 27 Member States helpdesks and ECHA
- Answer 'difficult' questions
- Ensure high quality and harmonisation
- Develop database of FAQs

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European Chemicals Agency- ECHA

- Day-to-day management of REACH
- IT systems
- Pre-Registration
- Registration
- Public Database
- Helpdesk
- Technical Guidance Documents

www.ec.europa.eu/echa

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Registration Guidance

- Part I: (general)
  - Scope and exemptions
  - Who has to register, what and when
  - How to prepare and submit dossier
  - Data sharing procedures
  - Duties of the Agency
- Part 2: (preparation of dossier)
  - Fulfilling info requirements
  - Generation of the dossier
  - When to update

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Guidance Available

- Intermediates
- Polymers
- PPORDS
- Substance Identity
- Pre-registration/data sharing

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Guidance-To be Published

- Substances in Articles
- Classification and Labelling
- Downstream Users
  - 2 sections available
  - Preparing for REACH and roles and obligations
  - ecb.jrc.it/reach

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Summary

- Support & Guidance is available
- REACHRight website - www.reachright.ie
- HSA helpdesk
  - Lo-call: 1890 289 389
  - E-mail: reachright@hsa.ie
- Irish Industry - www.reachaid.ie
- ECHA – guidance and helpdesk

  www.ec.europa.eu/echa

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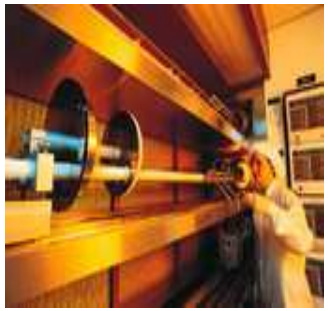

Concluding Remarks

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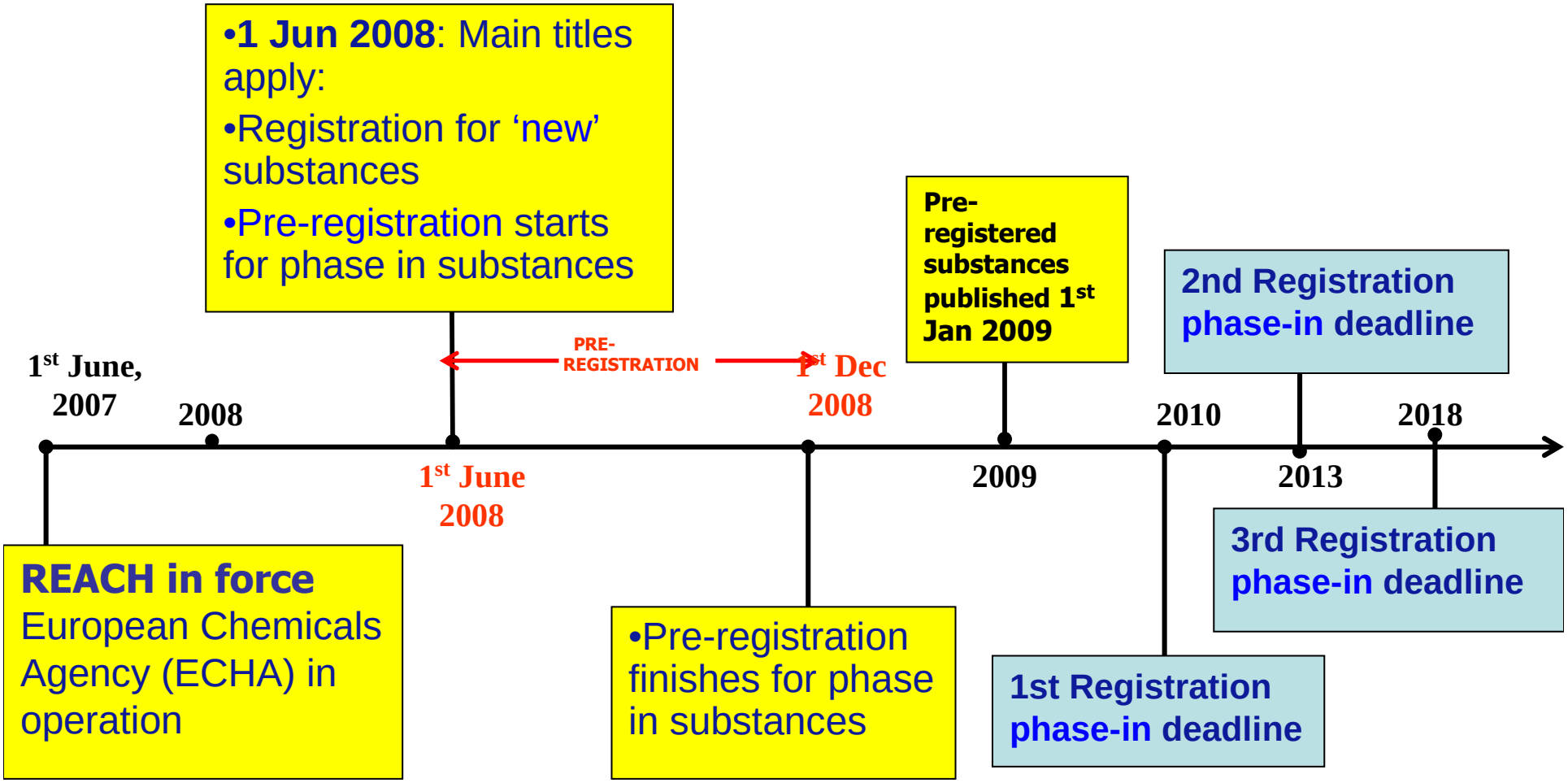
REACH – Implementation Timetable



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Start preparing now!

Initial steps for Industry preparation

- Get informed; monitor emerging guidance
- Develop inventory of all substances and uses
- Determine your role for each substance
- Communicate with suppliers, distributors, DUs
- Determine if you need to pre-register
- Identify appropriate contact person

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Concluding Remarks

- Start preparing NOW
- Communicate, communicate, communicate!
- Focus on the first steps.
- Pre-registration is an opportunity NOT to be missed!
- Support & guidance are available

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Available supports

- Authority Helpdesk:
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  - Email: reachright@hsa.ie
  - Web: www.reachright.ie

- EHCA (http://ec.europa.eu/echa/)
  - Guidance & Helpdesk

- REACHAID (www.reachaid.ie)

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Thank you

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