Communication in the Supply Chain under REACH

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Communication in the Supply Chain under REACH

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

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What is REACH?

- EU Regulation – *R*egistration, *E*valuation, *A*uthorisation and Restriction of *Ch*emicals
- One system across the EU
- Greater responsibility on industry to manage risks
- In principle, REACH applies to all chemical ***substances***

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Key Elements

- **R**egistration of all substances > 1 tonne/yr
- **E**valuation of some substances
- **A**uthorisation only for some substances of very high concern
- **R**estrictions - the safety net (Community wide action)
- **I**nformation in the **S**upply **C**hain- applies to all

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Key Timelines

June 1 2007: In force

June 1 2008: European Central Agency

June 1 2008: Main Titles of REACH apply

June -Nov 2008: Pre-Registration

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Who has to register?

EU **manufacturers** and **importers of substances**, on their own or in preparations, at greater than 1 tonne per annum

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REGISTRATION

- Registration requires M/I to:
  - Generate/collect information on substances
  - Use data to assess risks
  - Develop appropriate Risk Management Measures
- Information requirements increase according to quantity & risk
- Framework to demonstrate adequate control

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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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Registration of Low Volume Substances (1-10 tpa)

- Basic information on human health, physical and environmental hazards
- Classification & labelling (C&L) determined.
- Guidance on safe use – via MSDS
- NO CSA or Exposure Scenarios

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Registration of High volume Substances (> 10 tpa)

- More information on hazards
- C&L
- Chemical Safety Assessment (CSA)
- Exposure Scenarios developed and attached to MSDS for *dangerous* substances

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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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Registrant must

- Compile CSA at > 10t/yr
- Ensure risks are adequately controlled
- Develop exposure scenario (ES) and 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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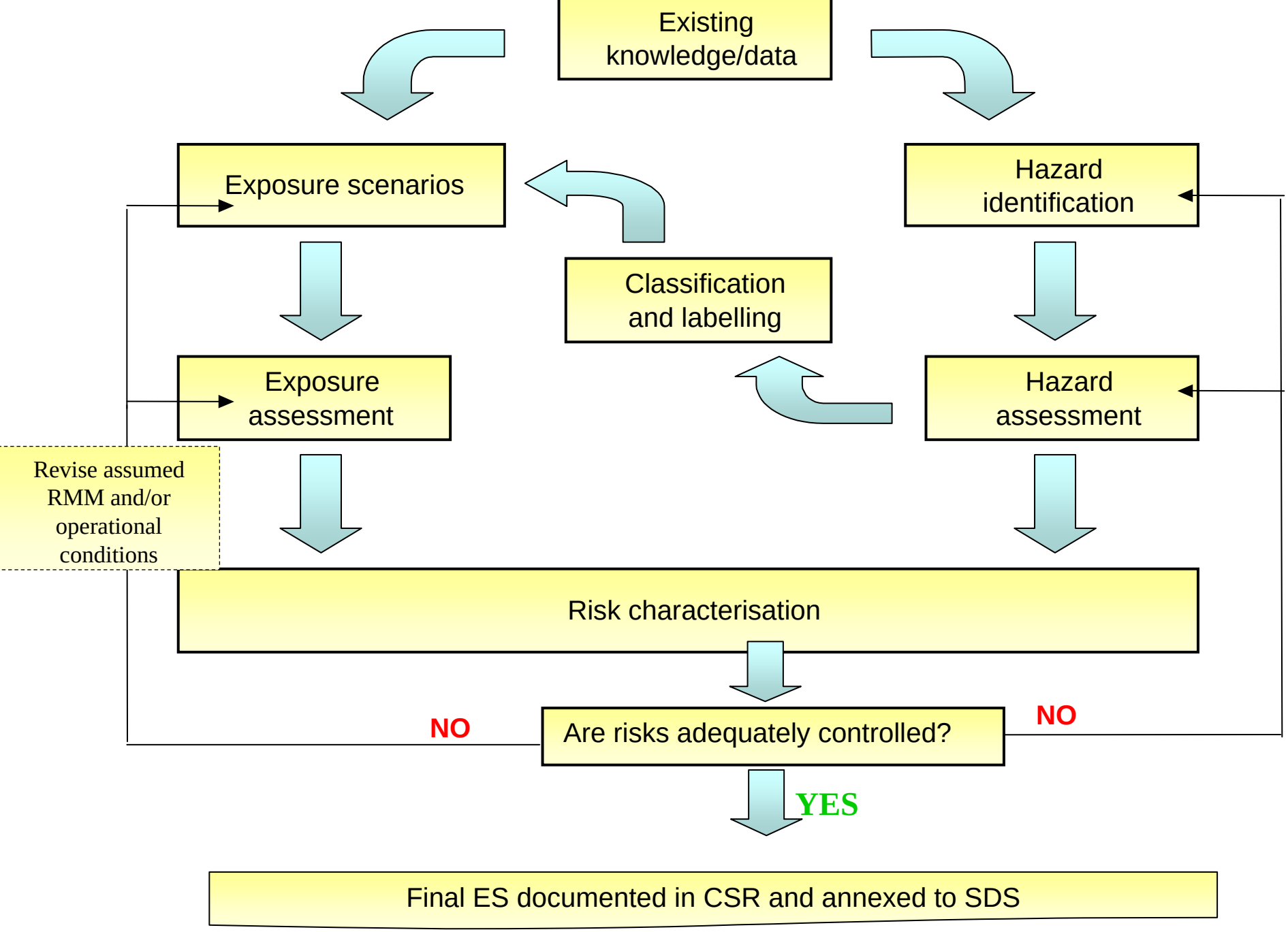
Existing knowledge/data
Exposure scenarios
Hazard identification
Classification and labelling
Exposure assessment
Hazard assessment
Revise assumed RMM and/or operational conditions
Risk characterisation
NO
Are risks adequately controlled?
NO
YES
Final ES documented in CSR and annexed to SDS

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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Exposure Scenario Development

Map uses of substance
Compile information on conditions of use, RMMs
Build initial ES
Run first exposure estimation (Tier 1 tools)
Seek feedback from representative Downstream Users
Identify if additional information needed (tier 2 tools, measured data)
Carry out further CSA Iterations (if needed)
Conclude exposure assessment & risk characterisation
Group ES into Broad ES or Use and Exposure Category (UEC) if appropriate
Document Final ES (no further testing *or* testing proposed) Identified uses Uses advised against CSR Extended SDS

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Exposure Scenario for Cleaning Product

Short Title	**Washing and cleaning products for general public**
Description of process	**Cleaning agent for hard surfaces in kitchen -Dispensed onto surface using trigger spray & wiped off with cloth**
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 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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DNEL/DMEL

DNEL Derived No Effect Level

- Threshold Effects
- Sometimes a single DNEL will suffice
- In most cases, different DNELs required for different endpoints, routes of exposure and populations

DMEL Derived Minimum Effect Level

- Non-threshold Effects e.g. genotoxic mutagen or carcinogen

Do you need a DNEL when you have an OEL?

National OEL transposes an EU IOEL

- OEL can be used instead of DNEL where
  - Exposure route and duration are the same
  - Current scientific evidence supports adequate control by OEL

- DNEL must be derived where
  - Exposure route is different
  - Exposure duration is different
  - Exposed population is different e.g. consumers
  - Current scientific evidence does no support adequate control by OEL

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Risk Assessments under Chemical Agents Regulation and REACH

- RA under Chemical Agents Regulation covers exposure of workers to hazardous chemicals
- RA under REACH is broader
  - all chemicals at > 10 t/a
  - Workers
  - Consumers
  - Environment
  - Man via environment
- RA performed under Chemical Agents Regulation will be useful for compiling Worker Exposure Assessment under REACH

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Downstream User – Am I covered by my suppliers SDS?

SDS + Exposure Scenarios (ES)

Downstream User

Am I inside ES?

Yes → **Apply ES and pass down supply chain**

NO → **Make use known to supplier**

Source Alternative Supplier

NO → **Notify ECHA**

Do targeted DU CSR

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EEA Manufacture

EEA Manufacturer

Distributor

Formulator

End User

Downstream Users

End User

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Registrant: EU Manufacturer

Role for Formulators

- Is own use within suppliers ES?
- Pass on suppliers ES for substances in the preparation downstream ***or***
- Extract relevant information on operating conditions and RMM and consolidate into ES for the preparation

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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’
- Relevant sections of ES incorporated
- When do new requirements apply?

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Available supports

- Authority Helpdesk:
  - Lo-call: 1890 289 389
  - Email: reachright@hsa.ie
  - Web: www.reachright.ie
- EHCA (http://ec.europa.eu/echa/)
  - Guidance & Helpdesk
- REACHAID (www.reachaid.ie)
- Trade Associations

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Guidance

- Guidance on the CSA – due mid 2008
- Guidance on Downstream User requirements – available on ECHA website

- http://ec.europa.eu/echa/home_en.html

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Thank you

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