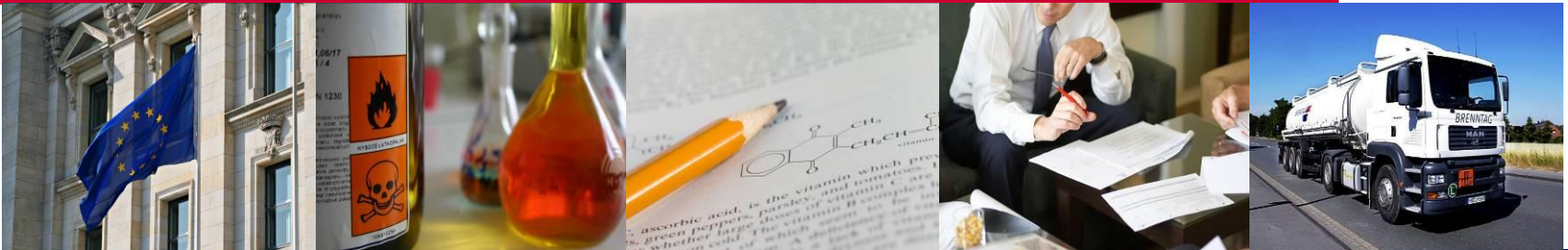


## REACH



## Exposure Scenarios & Downstream User Obligations

**Content**

- **Brenntag Group overview**
- **Brenntag's REACH strategy**
- **REACH terms and Definitions**
- **Major Steps and Timelines**
- **Safe Use and Exposure Scenario's (ES)**
- **Example of an Exposure Scenario**
- **Obligations for Downstream Users (DU)**
- **Exposure Scenarios for mixtures**
- **Summary**

Organisation

**Brenntag Group**

Global Sales

**€7.6bn (2010)**

Regions

**Europe, North America, Latin America, Asia-Pacific**

Activities

**Industrial & Specialty Chemicals**



▶ Oil & Gas

▶ Cosmetics

▶ Metal

▶ Pharmaceutical

▶ Plastics

▶ Personal Care

▶ Chemical Processing

▶ Food Ingredients

▶ Paint & Coatings

▶ Animal Feed

▶ Water Treatment

▶ Adhesives & Sealants

▶ Textile & Leather

▶ Cleaning

▶ Rubber & Latex

▶ Pulp & Paper



- Head Office
- Distribution Depot
- Specialty Site
- Manufacturing Site



## Headline facts:

- 18 strategic sites in UK & Eire
- Group turnover circa £300m
- 150 owned vehicles
- 880 employees
- 18,000 live customers
- 800 Suppliers
- 3000 Substances

## **Mission Statement**

**Ensure REACH Compliance in such way that our customers, our suppliers and authorities recognise Brenntag as the best prepared distributor**

## **Strategy**

- ✓ **Ensure own REACH compliance**
- ✓ **Provide professional REACH knowledge**
- ✓ **Provide efficient and effective Supply Chain Communication**
- ✓ **Provide expertise in Handling & Practice of Exposure Scenarios**

## Terms and Definitions (I)

**Use:** In general, a 'use' is any activity carried out with a substance as such or in a preparation, which could lead to an exposure to that substance

**Identified Uses:** are named in the safety data sheet, under heading 1. Their naming should be consistent with, but not necessarily the same as, in the title of the exposure scenario.

**Conditions of Use:** The conditions of use specify which parameters determine the exposure in a use. They include: the operational conditions, the risk management measures, concentration in a preparation or an article and the physical state (powder, liquid etc) and information on the surroundings in which the substance is used

**Operational Conditions (OC):** The operational conditions are part of the exposure scenario and aim to specify the circumstances of use of a substance or preparation. In particular, they describe the types of activity to which the exposure scenario relates, how frequently, how often and for how long a substance is used and in which type of process, at which temperatures etc.

**Risk Management Measures (RMM):** means an activity or device that reduces or controls the exposure of humans or the environment to a substance during its use as such, in a preparation or an article (e.g. exhaust ventilation, waste gas incinerators, use of personal protective equipment, such as gloves or masks)

**Scaling:** The aim of scaling is to allow flexibility in checking if your own or your customers' uses are covered by an exposure scenario. If you have another combination of operational conditions and risk management measures which allow you to achieve the same level of safety, you can use scaling to demonstrate that you are in compliance. You can use "scaling" only when options and limitations of scaling are communicated by the supplier in the ES.

## Terms and Definitions (II)

**CSA:** the Chemical Safety Assessment assesses the intrinsic hazard of a substance, assesses the emission/exposure resulting from manufacture and use of a substance, characterises the risk following such exposure and identifies and documents the conditions of safe manufacture and use.

**CSR:** the Chemical Safety Report documents the results of the CSA

**SDS:** the Safety Data Sheet provides comprehensive information about a substance or mixture for use in workplace chemical control regulatory frameworks. Both employers and workers use it as a source of information about hazards, including environmental hazards, and to obtain advice on safety precautions. The SDS is product related.

**ES:** the Exposure Scenario describes the conditions under which a substance can be used safely (= risks are controlled). It includes a short title (to label the content and applicability of the ES), the operational conditions and the risk management measures needed.

**extSDS:** Extended Safety Data Sheet (extended by the ES)

For **more detailed information** please also refer to:

–The ECHA Guidance for Downstream Users

[http://guidance.echa.europa.eu/docs/guidance\\_document/du\\_en.pdf?vers=29\\_01\\_08](http://guidance.echa.europa.eu/docs/guidance_document/du_en.pdf?vers=29_01_08)

–Your national helpdesk

–Your industry association

**Pre-registration**

Free of charge pre-announcement of substances to be registered in order to benefit from transition period for **manufacturers and importers**

**Finished now other than for new imports or manufacture over 1 ton – “late pre registration”**

**Registration**

**Manufacturers/Importers have to compile a Registration Dossier for each substance.** It contains information on the physicochemical, health and environmental properties of their substances and a Chemical Safety Report (CSR) which demonstrates safe use of the substance.

**Evaluation**

**ECHA** will check that the registration dossiers comply with the requirements and perform detailed dossier evaluation.

**Authorisation**

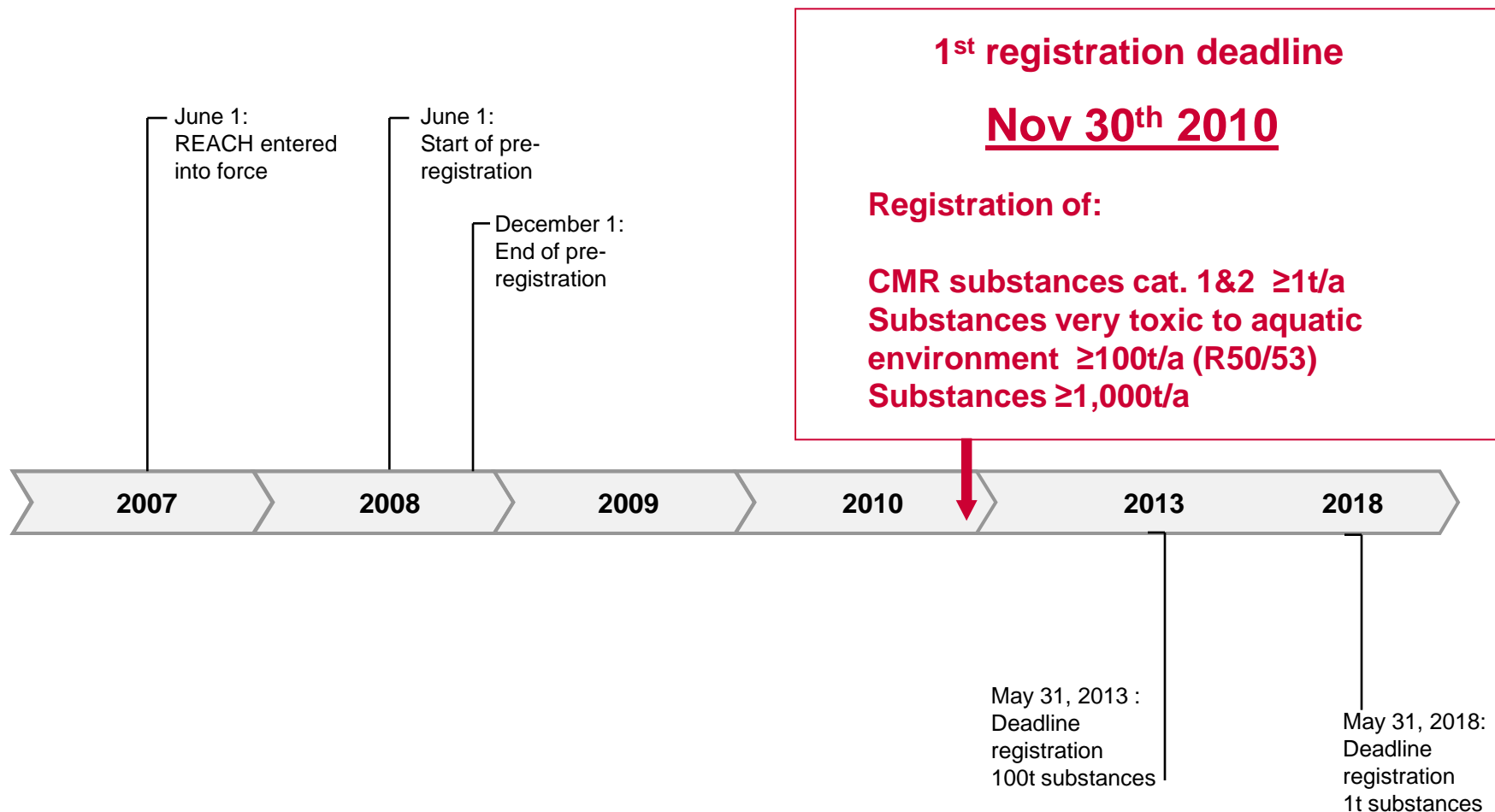
Use specific **Authorisation** is needed for Substances of Very High Concern

**Communication  
in the supply  
chain**

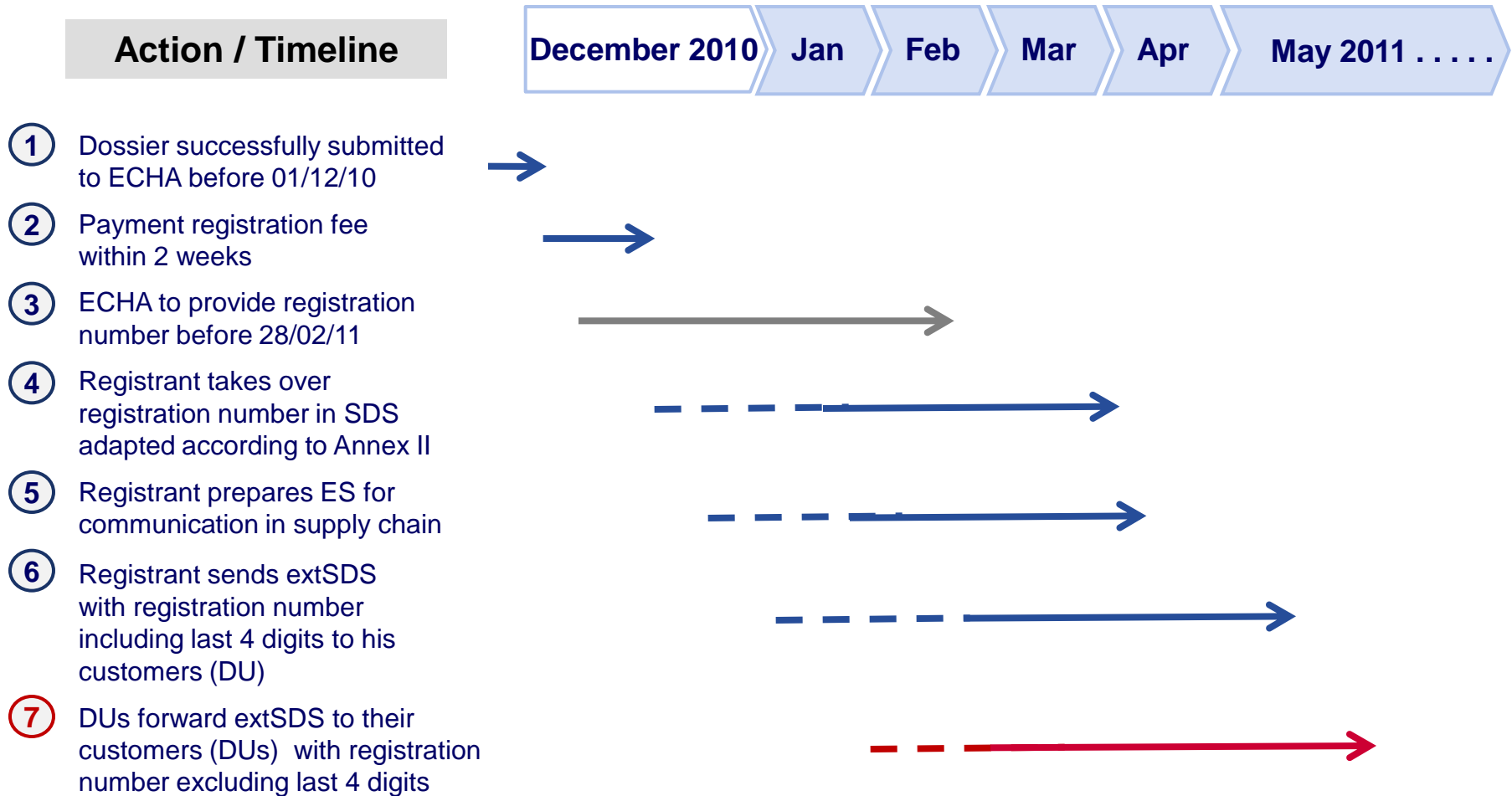
**Suppliers** of substances must pass on information on the health, safety and environmental properties and safe use of their chemicals to their Downstream Users via **Exposure Scenarios**.

**Handling & Practice  
Exposure Scenarios**

- **Inform our customers about their rights and obligations**
- **Co-develop European standard format for exchange of Exposure Scenarios**

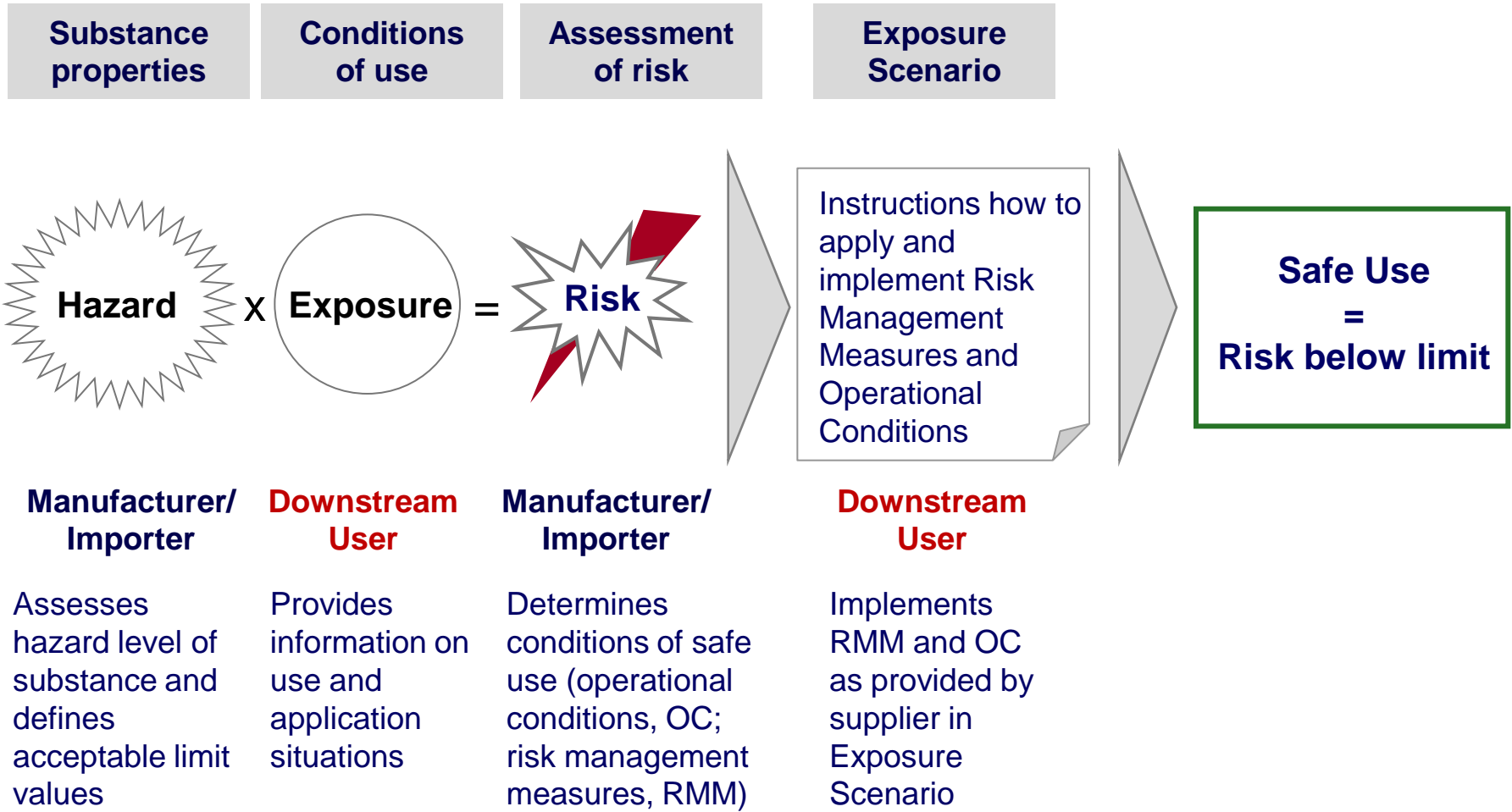


# From Registration to Exposure Scenario



**It is only now the first deadline has passed that Downstream Users Obligations begin**

The concept of Safe Use



## Safe Use and implications for Downstream Users (I)

- The **use of chemicals** (substances and mixtures) can **lead to exposure** (contact of humans and the environment with substances in different ways)
- “Safe use” of chemicals is now **legally organised** via REACH
- “Safe use” means that **exposure levels** are so small that **no harmful effects** on humans or the environment are expected to occur
- “Safe use” means that **exposure levels** are adequately **controlled**



It is the **obligation of Downstream Users** to make sure that all their uses are declared safe

## Safe Use and implications for Downstream Users (II)

- The “safe use” of a chemical is **dependent on**:
    - **Properties** of the chemical
    - **Operational conditions** (OC)
    - **Risk Management Measures** (RMM)
  - **Downstream Users are in control** of their Conditions of Use and Risk Management Measures. They can adapt those in case of need.
  - Instructions on how to safely use a chemical are written down in an **Exposure Scenario** as part of SDS
  - These instructions are now **legally binding!**
- “If the Exposure Scenario stipulates gloves then the Downstream Users must wear gloves”

## Content and Goal of Exposure Scenario (ES)

An Exposure Scenario is needed if a substance is manufactured / imported at a **volume of  $\geq 10t$**  and if it is **hazardous**

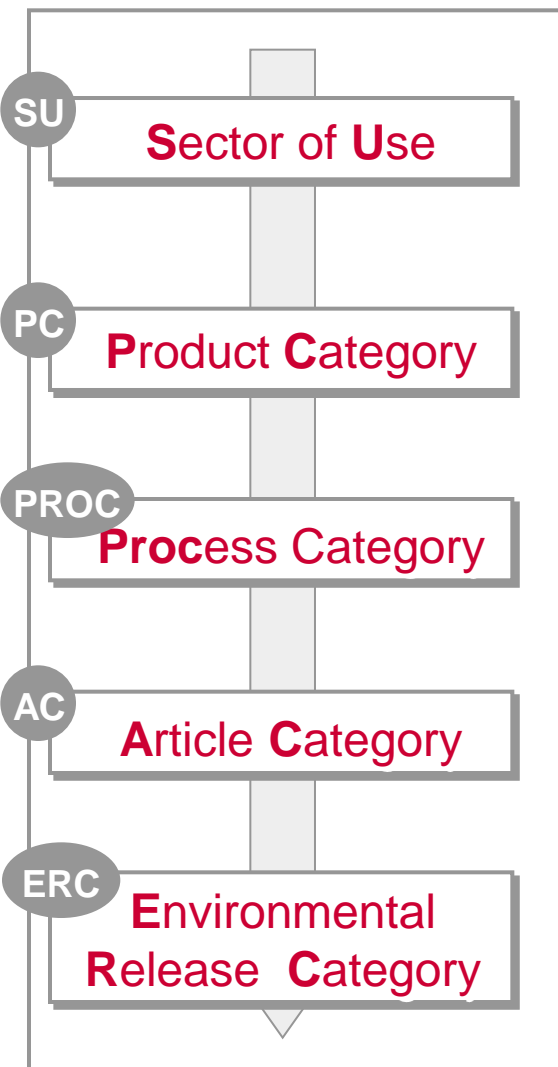
The Exposure Scenario documents results of the exposure assessment and risk characterisation

The Exposure Scenario is communicated with the new SDS (extended SDS "**extSDS**")

### Main elements of an ES:

- Describes conditions for safe use of substances during **entire life cycle**
- Covers the environment, workers and/or consumers
- Describes operational conditions (OC) determining the exposure (e.g. temperature during processing)
- Provides practical Risk Management Measures (RMM) needed to prevent, reduce or limit risks (e.g. wear gloves)
- Describes uses for which these conditions and measures are suitable
- One ES can cover one or more uses

Use Descriptor System



Indicator

Where the substance is used

Type of product the substance is used in

How the substance is used

Type of article the substance is used in

How the substance is released in environment

Rules

Industrial, professional, and/or Consumer and eventual supplementary sectors of end-use

Preparations/mixtures (by market sector)

Application techniques or process types for industrial and professional use

Article type in service life and waste life for consumers and workers

Conditions of use from environmental perspective



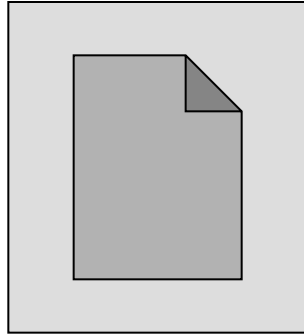
## Use Descriptors

Guidance on Information requirements and chemical safety assessment,  
Chapter R.12: Use descriptor system, version 2 March 2010

<b>3 Main user groups (<i>obligatory</i>)</b>	SU3 Industrial, SU22 Professional, SU21 Consumer
<b>Supplementary sector of use (<i>optional</i>)</b>	SU
<b>Process category (<i>obligatory for worker</i>)</b>	PROC
<b>Environmental release category</b>	ERC
<b>Product category (<i>PC or AC mandatory for consumer</i>)</b>	PC
<b>Article category (<i>PC or AC mandatory for consumer</i>)</b>	AC

## Examples of ES

### Acetic Acid



## ES Information structure

- **Guidance on Information requirements and chemical safety assessment, Exposure Scenario Format ..... Version May 2010 describes 4 standard formats**
  1. ES format for Worker use
  2. ES format for Consumer use
  3. ES format for service life and subsequent waste life stage (Workers)
  4. ES format for service life and subsequent waste life stage(Consumer)

**Note: Guidance only ! Not obligatory like 16 point SDS**

**Extended SDS from supplier is foreseen to include Exposure Scenarios covering all life cycle steps for a substance**

## Obligations for Downstream Users (DU)

What are my legal obligations as a Downstream User?

How can I check compliance as a Downstream User?

## Downstream User's legal obligations

### Art. 37 (5) of REACH Regulation:

Any downstream user shall identify, **apply** and where suitable, **recommend**, appropriate measures to adequately control risks identified in any of the following:

- (a) the safety data sheet(s) supplied to him;
- (b) his own chemical safety assessment;
- (c) any information on risk management measures supplied to him in accordance with Article 32.

### Art. 39 (1) of REACH Regulation:

Downstream users shall be required to **comply** with the requirements of Article 37 at the **latest 12 months** after receiving a registration number communicated to them by their suppliers in a safety data sheet.

**NOTE:** Above is an extract. For exhaustive list of legal obligation with respect to safe use and information in the supply chain please refer to REACH Regulation Title V "Downstream Users"

## Make compliance check

Each **Downstream User** of a substance or a preparation which is supplied together with SDS and Exposure Scenario(s) **must ensure that his use conditions are covered** by that scenario.

→ **Compare conditions described in the Exposure Scenario with own practices.**

- Your use is covered: your actual operational conditions and risk management measures correspond to those specified in the Exposure Scenario.
  - **No need for further action**
- Your use differs **marginally** from the Exposure Scenario:
  - **Follow instructions in ES how to adjust the variables to your own situation (scaling)<sup>1)</sup>**
- Your use differs **substantially** from Exposure Scenario:
  - **Please check options described on page 23**

1) If essential key parameters of the exposure estimation are known, the downstream user can vary and adapt these to his actual circumstances.. NOTE: Scaling is only possible if the supplier has specified relevant scaling tools or assessment instruments in his exposure scenario

## Downstream User compliance check

### 1 Check title section of Exposure Scenario (ES)

- Compare your use with the short title and the use descriptors given in the first section of the Exposure Scenarios
- Select ES with short title and use descriptors which (closest) matches your situation

**NOTE:** matching uses does not automatically ensure safe use, a second step of comparison is necessary

### 2 Check operational conditions (OC) and risk management measures (RMM)

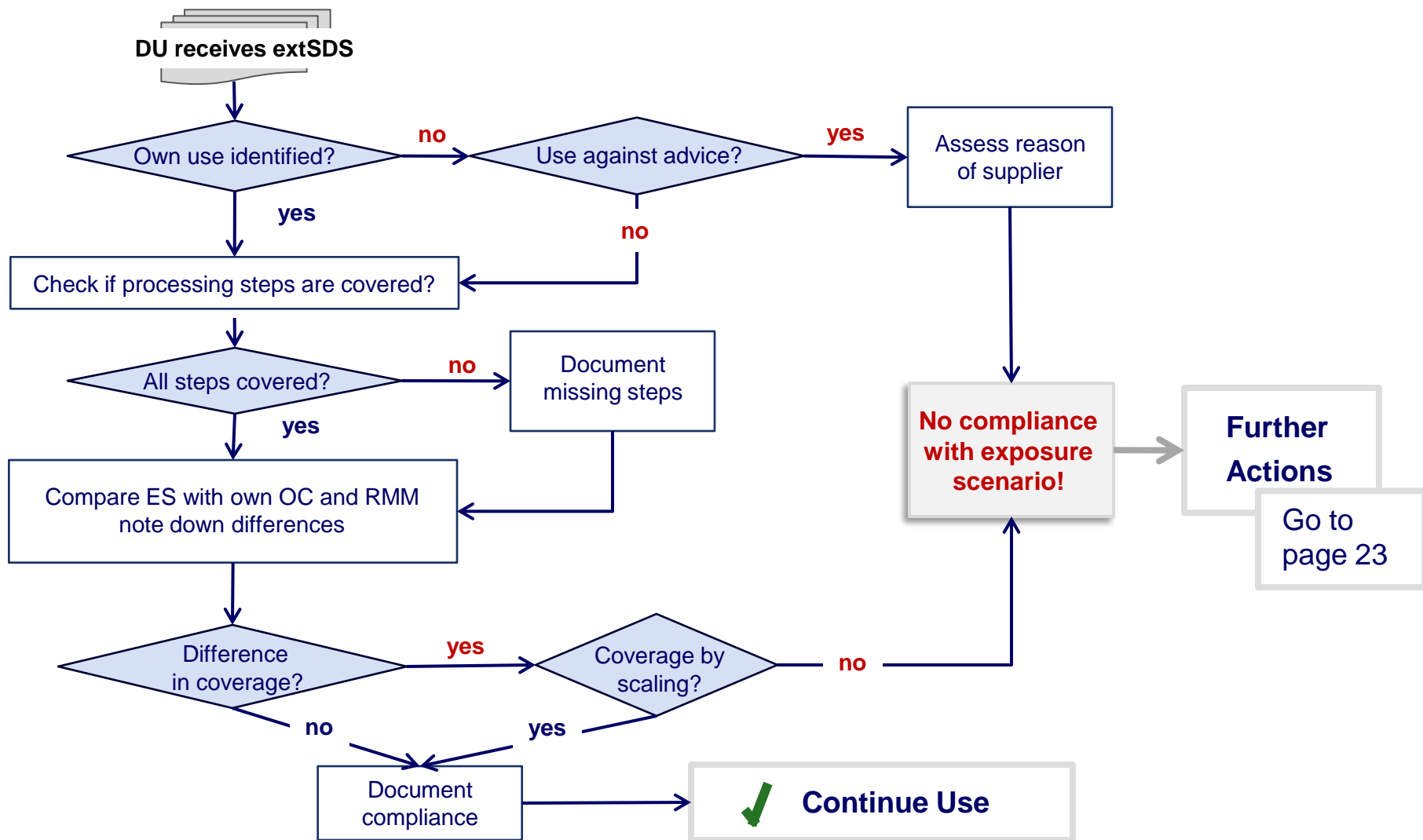
- Compare OC and RMM described in Exposure Scenario with your situation

**NOTE: instructions are legally binding!**

Note: If your use is not named in the safety data sheet or in the title of the exposure scenario, this does not necessarily mean that you are not in compliance with the obligations. You may use a substance or preparation for a use that is not identified as long as you comply with the conditions of use described in the Exposure Scenario.

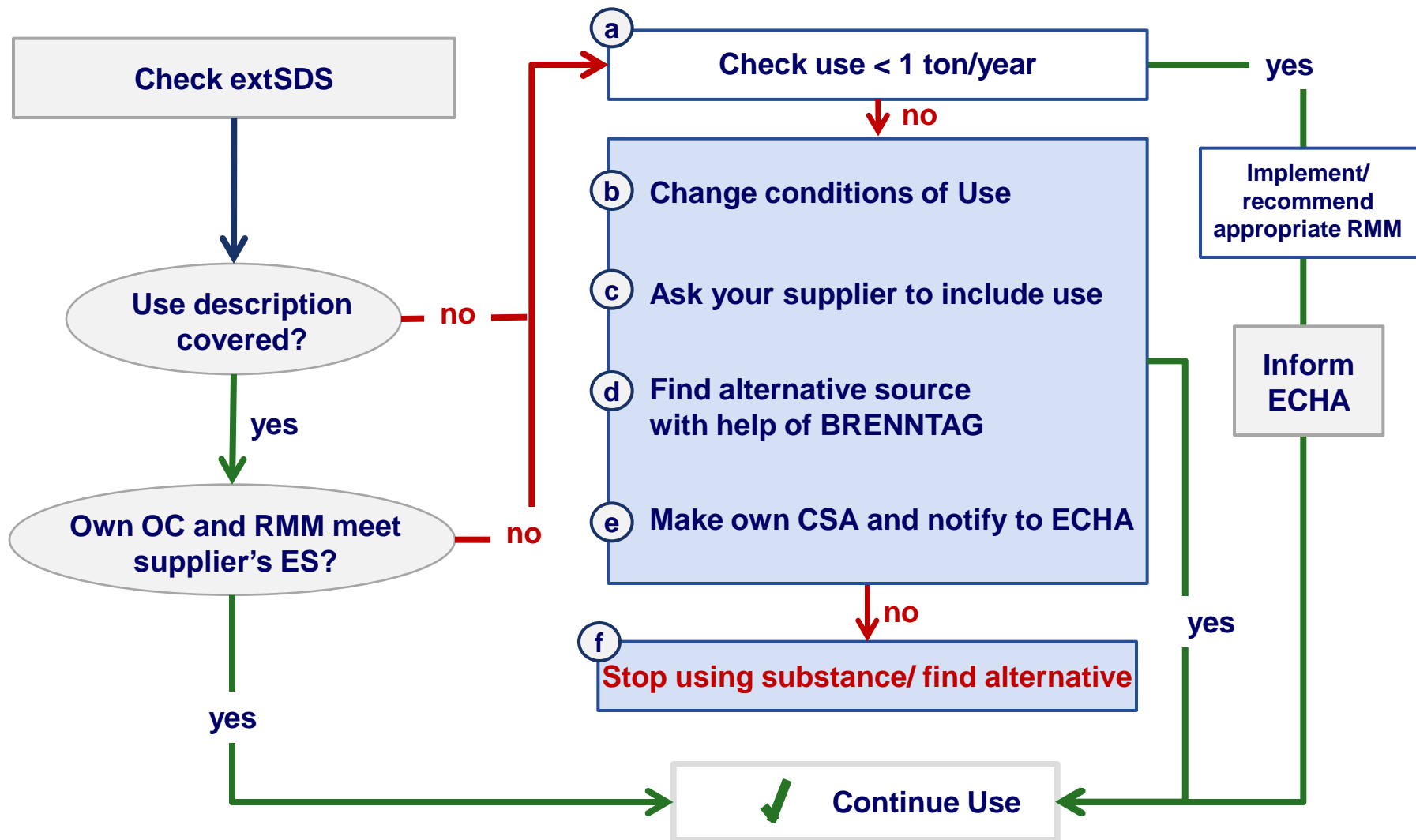
Guidance for DU pg 49 note b second paragraph

# How to perform Downstream User compliance check



Source: ECHA Guidance for downstream users, Page 49

Options when uses / conditions are not covered



## Exemption: use outside conditions below 1 ton per year

a

### A Downstream User does not need to perform a Chemical Safety Assessment for uses outside description in the ES if:

- The downstream user uses the substance or preparation in a total quantity of less than one ton per year – Art. 37(4) c)

However the Downstream User has to fulfill certain **obligations** if he wishes to rely on this exemption:

- He shall identify, apply (and if appropriate communicate) any appropriate risk management measures needed to ensure safe use [Art. 37(6)]
- He has to inform ECHA via REACH-IT about the exempt situation [Art. 38(1)] and provide information as specified in Art. 38(2)
- He has to **inform ECHA** within **six months** from receipt of a registration number provided by the supplier in a safety data sheet [Art. 39(2)]
- The amount used is not limited to the actually applied, but includes the amount stored as well

**NOTE:** Above is an extract. For exhaustive list exemptions please refer to REACH Regulation Art.37(4)

## A Downstream User will NOT receive ES for substances when:

- The substance is manufactured / imported at a volume of **below 10 tons**
- The substance is **not dangerous**<sup>1)</sup>
- The substance will be **registered at a later stage** (2013 or 2018)

### Notes:

Registration Numbers could be communicated via SDS earlier than Exposure Scenarios

1) Dangerous in this context means: dangerous according to the CLP Regulation (former "Dangerous Substance Directive" 67/548/EEC (DSD)) or Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) or substance of equal concern

## Registration Numbers

REACH Reference numbers have the following structure:

**< TYPE>-< BASE-NUMBER>-< CHECKSUM>-< INDEX-NUMBER>** where:

**< TYPE>**: Is a 2-digit number giving the type of number:

- 01 Registration
- 02 C&L notification
- 03 Substance in article
- 04 PPORD
- 05 Pre-registration
- 06 Inquiry
- 07 On-site isolated intermediates
- 08 Transported on-site isolated intermediates
- 09 Data holder notification
- 17 Late pre-registration

**-< BASE-NUMBER>**: Is a 10-digit number

**-< CHECKSUM>**: Is a 2-digit number

**-< INDEX-NUMBER>**: is a 4-digit number giving the index of a member in a joint submission.

Example 1: **05-2114083396-41-0000**

Example 2: **01-0000017295-68-XXXX**

Example 3: **17-2119582429-26-0000**

## The legal time lines

From receipt of Registration Number provided in safety data sheet:

- Downstream Users have **12 months** to **examine** own uses and to **comply with** stipulated Operational Conditions and Risk Management Measures
- Downstream Users have **6 months** to **inform ECHA** about any use of a substance outside conditions described in ES if he intends to perform an **own CSA**
- Downstream Users have **6 months** to **inform ECHA** about **uses below 1 ton/year** which are not covered by an ES

**Brenntags recommendation:** Start checking uses immediately after you have received registration number and ES in order not to lose time if you have to prepare your own CSA

## Exposure Scenarios for mixtures

- Each individual substance present in a mixture may have more than one Exposure Scenario
- Different registration time lines for individual substances will trigger “incomplete” extSDS

A mixture containing 3 individual substances with registration deadline 2010, 2013 and 2018 will be provided with ES for all ingredients by 2018+ only

- Multiple ESs can be aggregated when it will be clear how to do this<sup>1)</sup>

1) The DPD+ method that would be applied for aggregating ES is currently being reviewed by formulators

## Summary

# extSDS includes the Exposure Scenario



## Details Conditions for use

(to sufficiently protect human health and the environment)

Includes:

- **Approved Uses**
- **Risk management measures**
- **Operational conditions**

**+** **Uses advised against**

## Summary

- REACH is the legal framework that “organises” the safe use of chemicals
- The “safe use” of chemicals means that exposure levels are adequately controlled by Manufacturers and Downstream Users
- Downstream Users are in control of their Conditions of Use and Risk Management Measures. It is the legal responsibility of the Downstream User to ensure “safe use”
- Instructions how to safely use a hazardous chemical ( $\geq 10t$ ) are communicated in the Exposure Scenario and are legally binding
- Not all substances will be provided with an ES in 2011
- When you receive an ES you have to compare the operational conditions and risk management measures described in the ES with your own practices
- In case your own practices deviate from these, you can choose from several options to become compliant
- The regulation grants you a period of 12 months from receipt of registration number communicated via SDS to become compliant
- Exposure Scenarios belonging to a mixture cannot yet be aggregated into one ES



There is no standard format for the Exposure Scenario



Thank You

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**Tel: 00 44 (0) 113 3879 342**

**REACH beyond** 