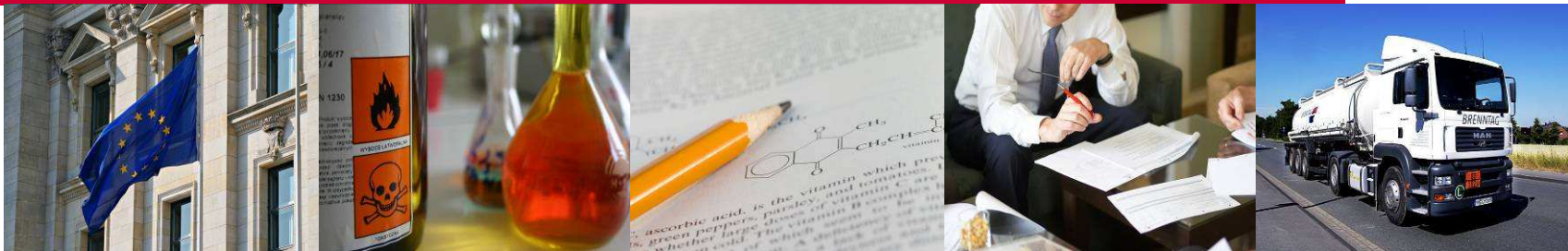


BRENNTAG

Exposure Scenarios: Obligations for Downstream Users



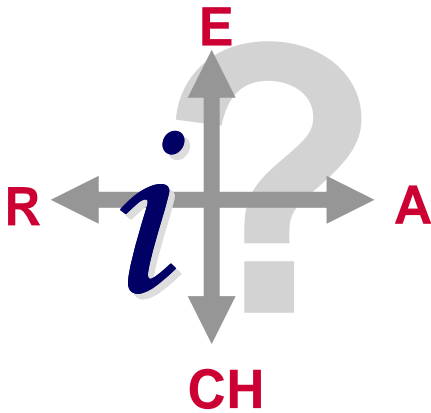
Customer Package - January 2011

REACH beyond 

Disclaimer

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Objectives



Give answers to

- What is an Exposure Scenario?
- What are the rights and obligations of Downstream Users?
- How can Downstream Users demonstrate “Safe Use” ?

Content

Safe Use and Exposure Scenario (ES)

Obligations for Downstream Users (DU)

Uses not covered

Time lines

Example of an Exposure Scenario

Exposure Scenarios for mixtures

Enforcement

Back-up: Terms & Definitions

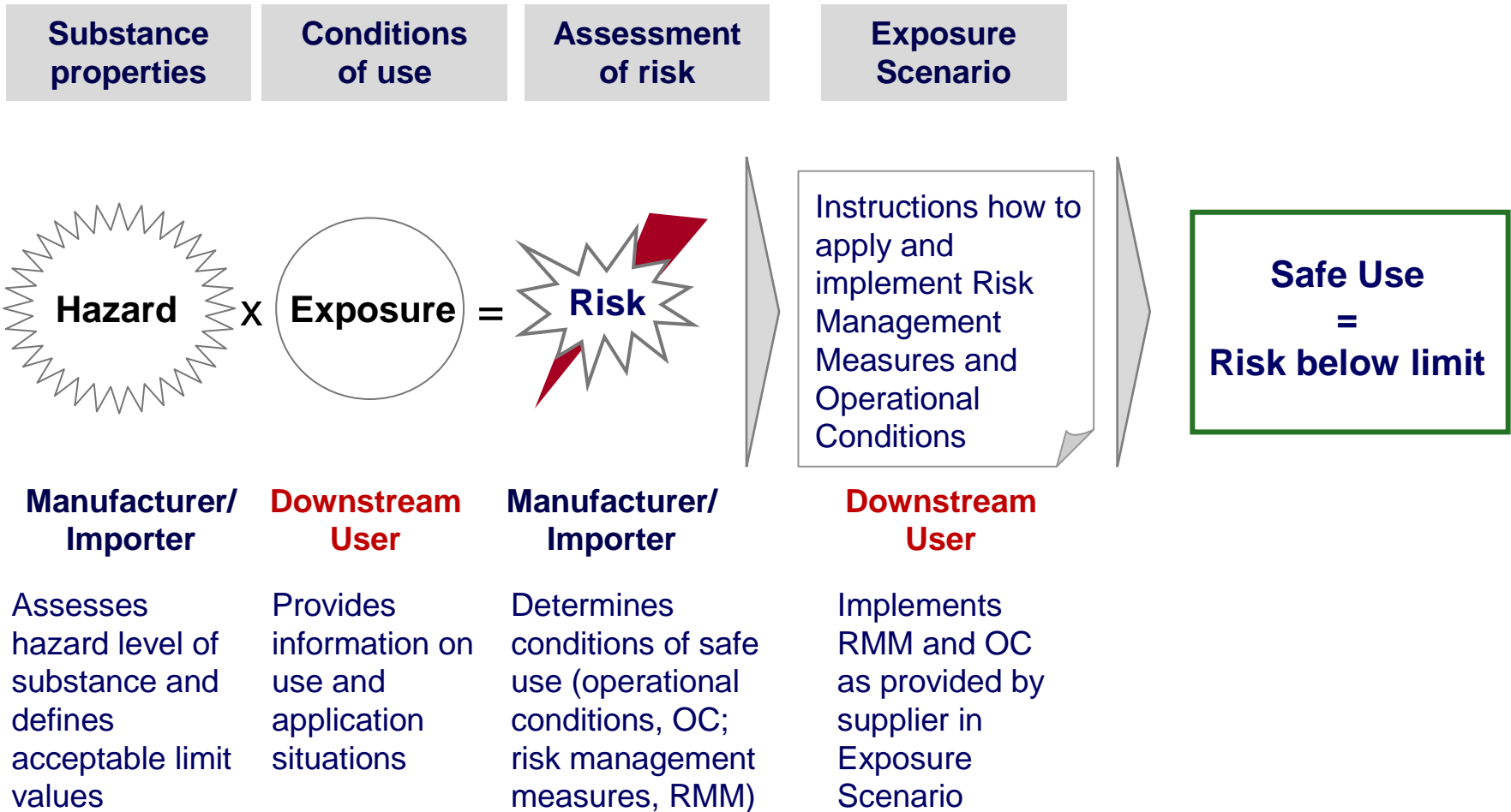
Safe Use and Exposure Scenarios

What is the concept of Safe Use?

What is the content of Exposure Scenarios?

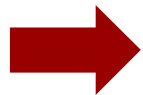
What are the reasons for not receiving an Exposure Scenario?

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 organized** 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**

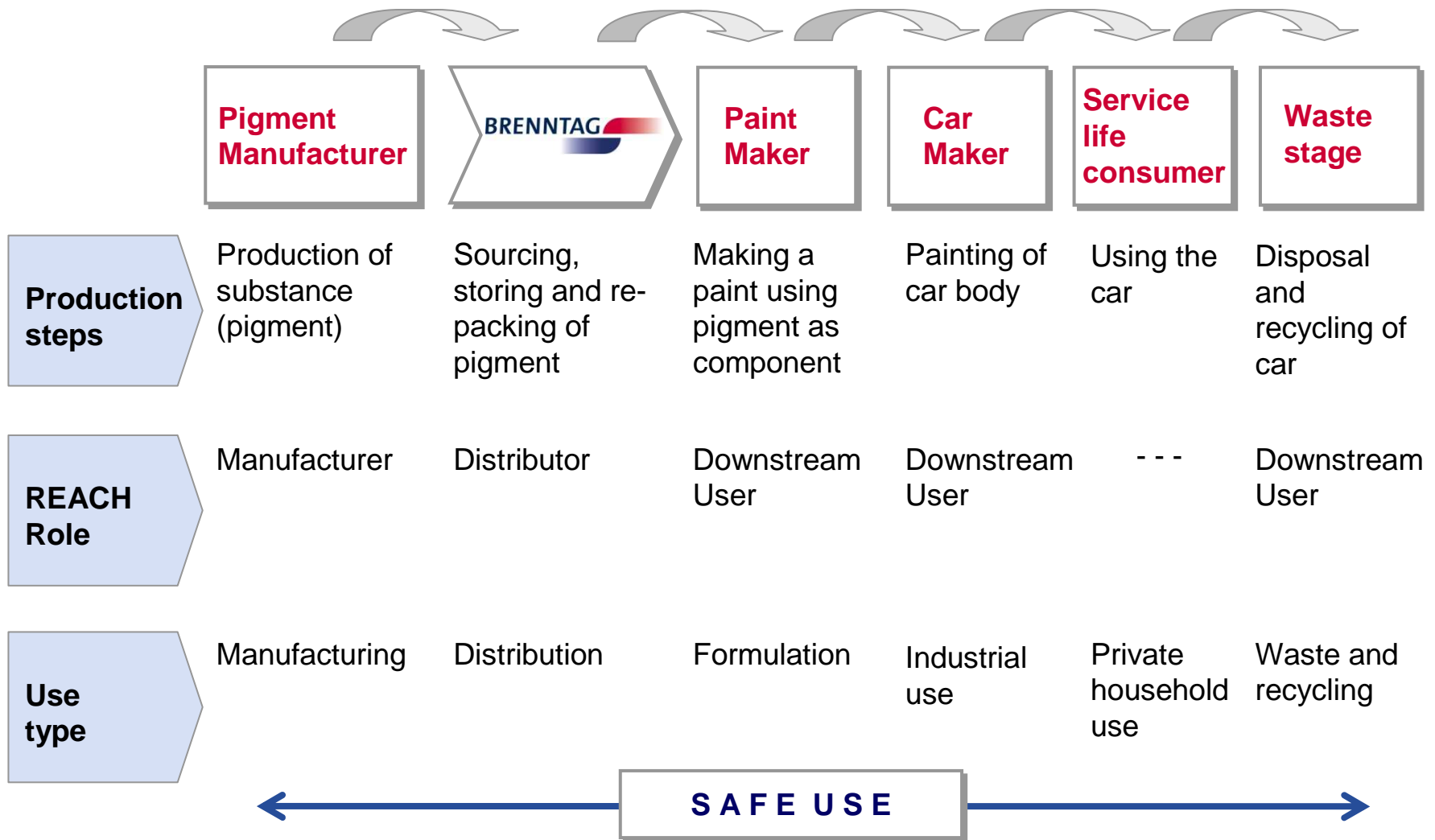
The Exposure Scenario documents results of the exposure assessment and risk characterization

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

Life cycle of a substance



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**¹⁾
- 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

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)¹⁾**
- Your use differs **substantially** from Exposure Scenario:
 - **Please check options described on page 17**

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

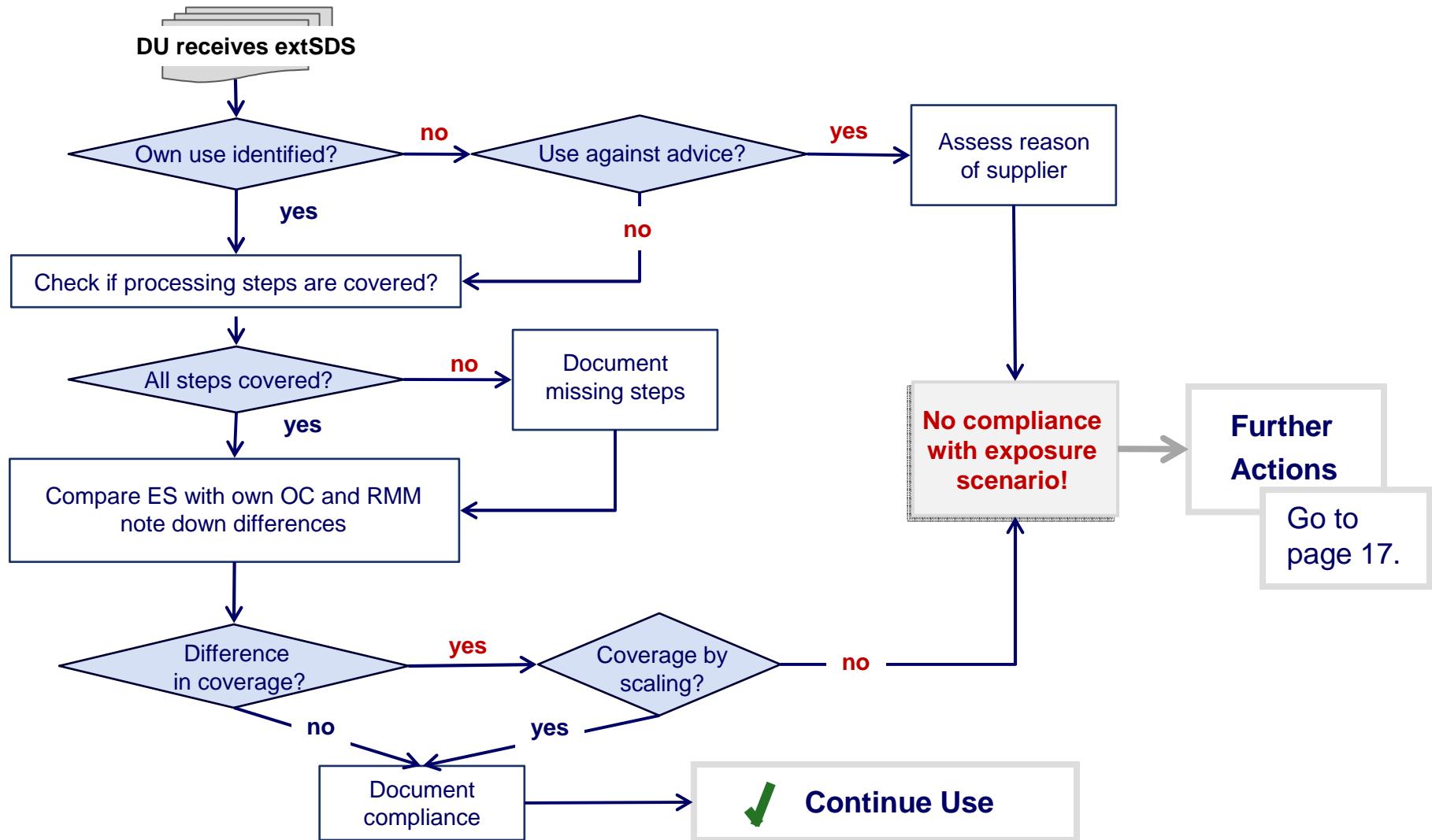
NOTE: matching uses does not automatically ensure safe use, a second step of comparison is necessary

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!

How to perform Downstream User compliance check



Source: ECHA Guidance for downstream users, Page 49

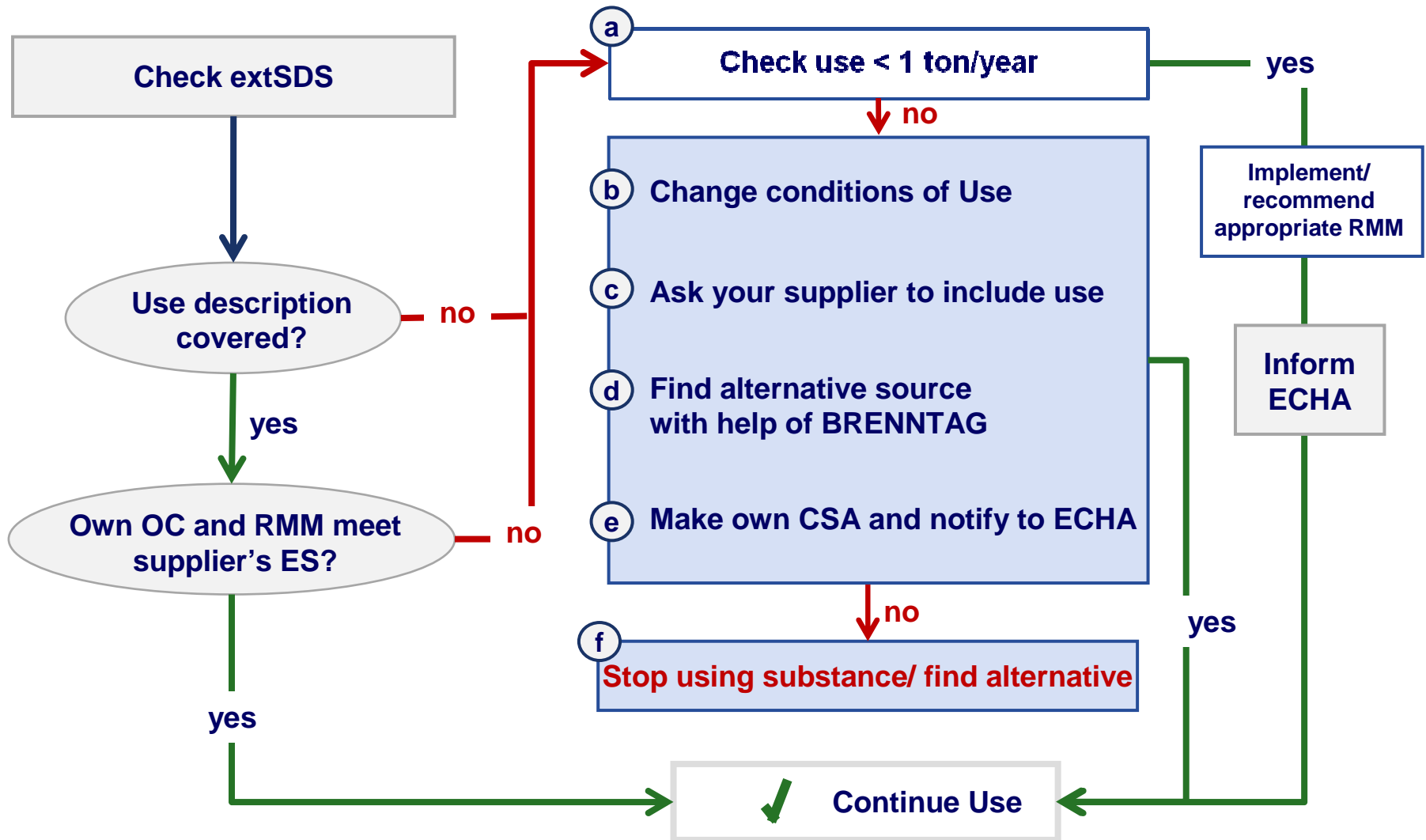
Uses not covered

What are my options if my use is not covered?

Which actions do I have to take to ensure compliance?

What is the situation if my volume of use is less than 1 ton/year?

Options when uses / conditions are not covered



Possible actions to ensure compliance

- (b) Change conditions of use:** If your operational conditions and/or your implemented risk management measures do not meet OC/RMM recommended by your suppliers' ES, you can modify your OC/RMM to meet those described in ES.
- (c) Ask supplier to include use:** After checking you find out that your use is not covered, you might contact your supplier and ask him to include your additional use in his ES. **Note:** The supplier is not legally obliged to take up additional uses.
- (d) Find alternative source:** In some cases it might be easier to find an alternative source which supports your use in his ES. Ask BRENNTAG for assistance.
- (e) Make own CSA:** When **above options fail** or your use is confidential, you can ensure compliance by preparing your own Chemical Safety Assessment (CSA) as a DU.
Note: In this case you have the obligation to inform ECHA (free of charge) about your own CSA within 6 months from the receipt of the extSDS. Your CSA is for your records. Authorities may ask you for it.
- (f) Stop using the substance:** In certain cases you might deem it inappropriate to continue to use the substance. Ask Brenntag for assistance in finding a substitute.

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

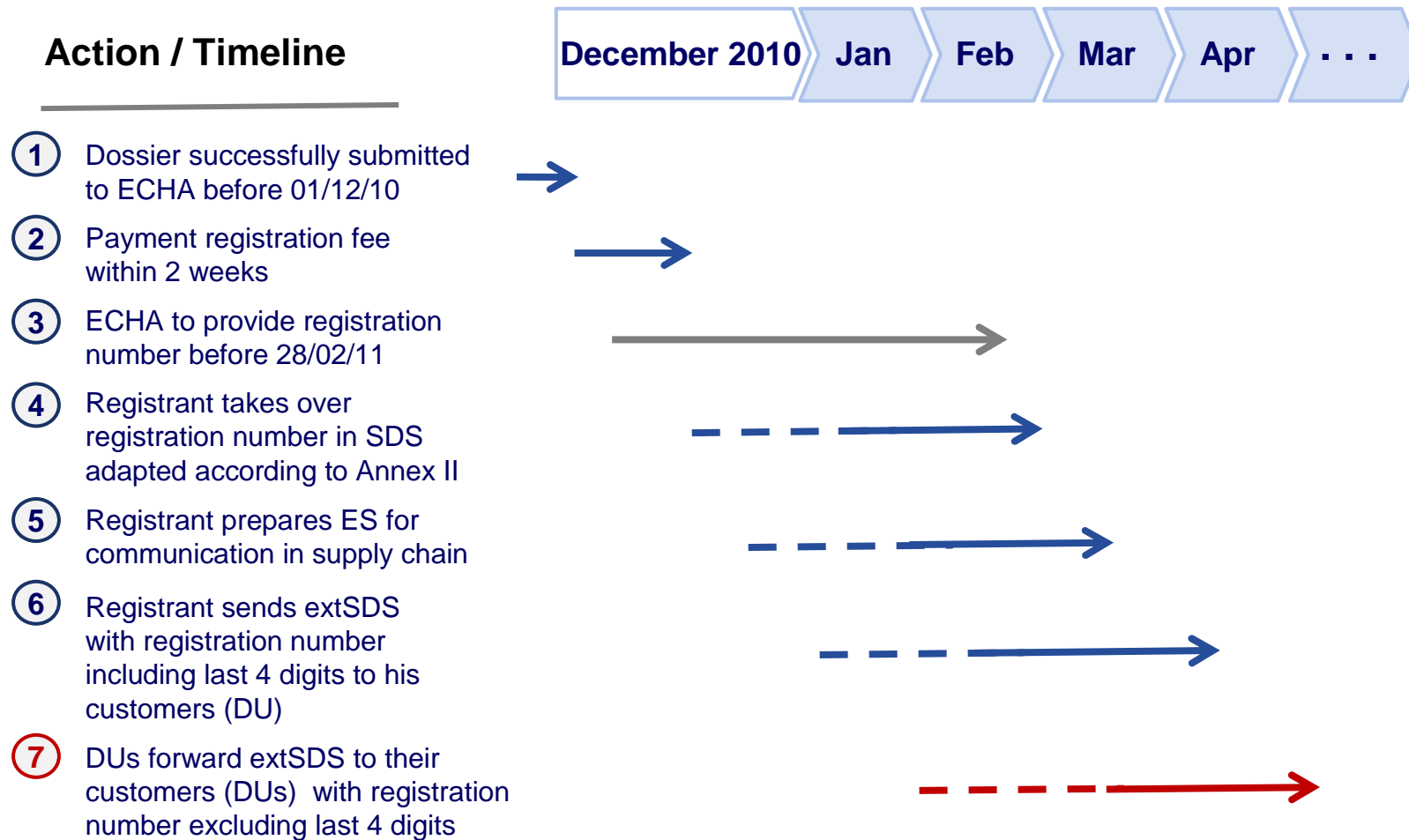
NOTE: Above is an extract. For exhaustive list exemptions please refer to REACH Regulation Art.37(4)

Timing

What are the milestones from registration to Exposure Scenario?

What are the legal time lines?

From Registration to Exposure Scenario



The supply of extSDS including registration numbers to Downstream Users might take a few months from registration date.

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

REMARK: Start checking uses immediately after having received registration number in safety data sheet in order not to lose time in case you have to prepare 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 this¹⁾

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

Enforcement

- European enforcers announced they will **check Formulators** in Spring 2011
- What can be asked?
 - Imports: Have you (pre)-registered? Are you covered by OR?
 - extSDS: Have you received extSDS ?
 - Exposure Scenarios: Have you matched your uses? Have you checked your Operational Conditions and Risk Management Measures?
- What can be enforced at Downstream Users/Formulators in Spring 2011?
 - Nothing! DUs have 12 months to implement OC and RMM after reception of the extSDS from their supplier.
 - If a use is not covered the DU must correct the situation within 12 months after reception of the extSDS while the use can be continued.
- The new Forum enforcement project “REACH-EN-FORCE 2” aims to ensure compliance with duties placed on formulators of mixtures as they have important responsibilities further down the supply chain for many essential requirements imposed by the REACH and CLP Regulations.
- In addition, the inspectors will raise awareness of the future obligations for Downstream Users with relation to the extended safety data sheet.

The ECHA press release regarding enforcement can be found [here](#)

Summary

- REACH is the legal framework that “organizes” 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 among 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

Back-up

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, characterizes 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.

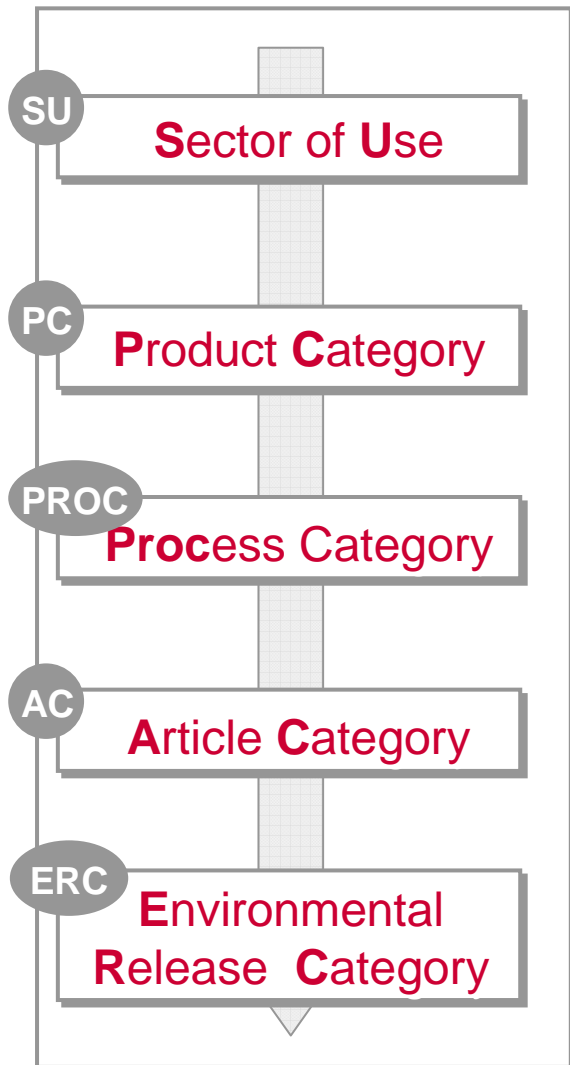
ES: the Exposure Scenario describes the conditions under which a substance can be used safely (= risks are controlled). It includes a short title (to label the content and applicability of the ES), the operational conditions and the risk management measures needed.

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)
- Your national helpdesk
- Your industry association

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



For further information on use descriptors please refer to ECHA document "Guidance on Information Requirements – Part D-3 and D-4
 Link: http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf?vers=20_08_08

Recommendations for assigning Use Descriptors: step 1

Select appropriate sector of use

Choose among the following mandatory descriptors:

- **SU3:** industrial uses (e.g. bleaching chemical in paper industry)
- **SU21:** private household uses (e.g. painting the wall as a private person)
- **SU22:** professional uses (e.g. painting house on commercial basis)

Supplementary descriptors for Sectors of end use may be added

Recommendation for assigning Use Descriptors: step 2

According to your SU selection assign additional descriptors applying the following rules

- **[SU3] – Industrial use:** assign at least process category (PROC) and environmental release category (ERC)
- **[SU22] - Professional use (worker's end-use):** assign at least process category (PROC) and environmental release category (ERC)
- **[SU21] - Consumer end-use:** assign product category (PC) or article category (AC) and environmental release category (ERC)

A substance in its life cycle: pigment in paint for industrial car painting

