REACH Regulation

a short introduction

A4 REACH

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- REACH processes
- REACH main actors
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WHO IS THIS PRESENTATION FOR?

This is an introductory presentation of REACH Regulation for:

- those that are not involved in detailed work with REACH

- OSH professionals
- OSH officials
- Managers

- those that want to have an example of introductory training about REACH

- beginners/juniors that will work with REACH in detail and need an introduction

Aim of the presentation: allow better navigation through REACH

Source: https://elcomercio.pe/eldominical/burnout-noticia-642721-noticia/

REACH OVERVIEW

REACH = Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

REACH objective : improve the protection of human health and the environment whilst maintaining competitiveness and strengthening the spirit of innovation in Europe's chemicals industry.

REACH established **ECHA**

Industry has the burden of proving that chemicals produced and placed on the market do not impose unacceptable risks for health and environment.

REACH OVERVIEW

REACH does not apply to:

- radioactive substances
- substances, mixtures, or in an article, which are subject to customs supervision (in transit)
- non-isolated intermediates
- the carriage of dangerous substances
- waste as defined in Directive 2006/12/EC

Avoids overlapping with other regulation

REACH OVERVIEW

- **REACH and famous :**

"no data no market"
"one substance one registration"
"Candidate List"
"Sunset Date" etc.

- **Specific approach** (though with general coverage): substance, tonnage, use, exposure

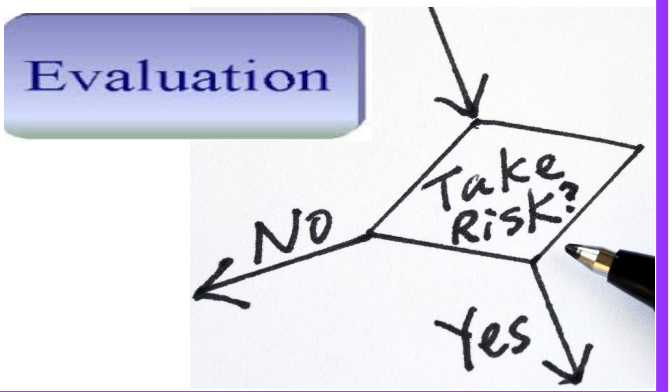
- **Descriptors and abbreviations**: ex. Sector of use (SU), Process category (PROC), Article Category (AC), Environmental Release Category (ERC), DU, RAC, CSA/CSR, ECHA etc.

- **Transparency** (with some confidentiality): ECHA publishes some of the data and information form registrants

- **Highly linked** to its own guidelines, to other regulations/authorities/agencies etc.

REACH PROCESSES

REACH has 4 main processes



AUTHORISATION

REACH PROCESSES

REGISTRATION

Substances that need to be registered:

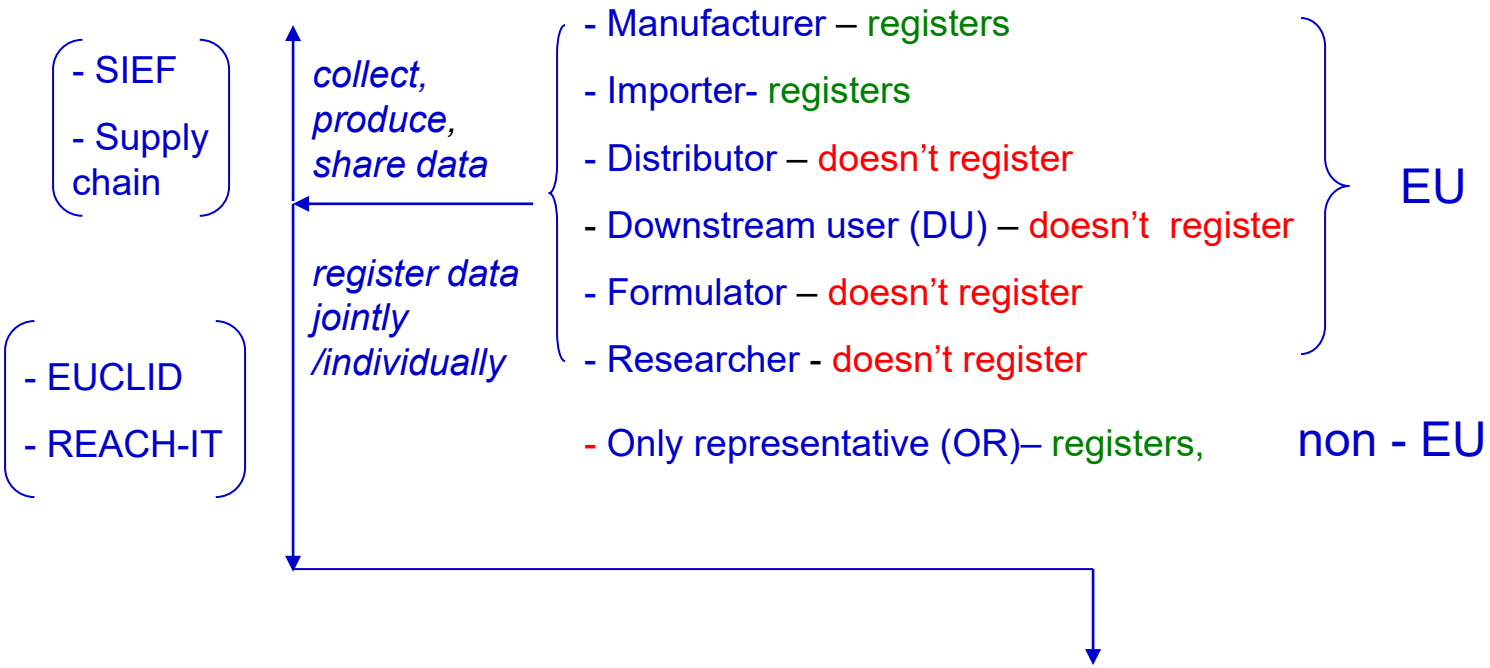
phase-in/non-phase-in substances manufactured/imported at 1t/y or more

phase-in substances are those manufactured or placed on the market before REACH entered into force.
phase-in substances fulfil at least one of the following criteria :
- are listed in the European Inventory of Existing Commercial Chemical Substances (EINECS)
- have been manufactured in the EU but have not been placed on the EU market after 1 June 1992
- qualify as "no-longer polymer‘

non-phase-in substances have not been manufactured, placed on the market or used in the EU before 1 June 2008, unless they were notified under the Dangerous Substances Directive 67/548/EEC.

REGISTRATION

“NO DATA … NO MARKET “



“ONE SUBSTANCE* …ONE REGISTRATION DOSSIER”

- Technical dossier
- Chemical safety report (CSR), if needed

*) in this presentation “substance” stands for substance on its own, in mixtures or in articles; for more info see REACH

REACH PROCESSES

REGISTRATION

Manufacturers and importers of the same substance have to submit their registration jointly **- one substance, one registration** principle.

There are two mechanisms for data sharing between registrants for a substance:

- Substance Information Exchange Fora (SIEFs), used for phase-in substances that have been pre-registered

- Inquiry, used for non-phase-in substances and for phase-in substances that have not been pre-registered

- Co-registrants will chose a Lead registrant

REACH PROCESSES

REGISTRATION

Registration dossier :

- **technical dossier :**
  - The identity of the substance
  - Information on the manufacture and use of the substance
  - The classification and labelling of the substance
  - Guidance on its safe use
  - Robust study summaries of the information on the intrinsic properties
  - Proposals for further testing, if relevant
  - An indication as to whether the information has been reviewed by an assessor;
  - Confidentiality issues
  - Exposure related information (main use categories, significant routes of exposure) for substances between 1 and 10 t/y.

- **chemical safety report (CSR)**, for substances at 10t/y or more, to present the chemical safety assessment (CSA) and demonstrate that risks from the exposure to a substance, along its life cycle, are controlled when considering a certain Exposure Scenario (ES) i.e. specific operational conditions and risk management measures are applied.

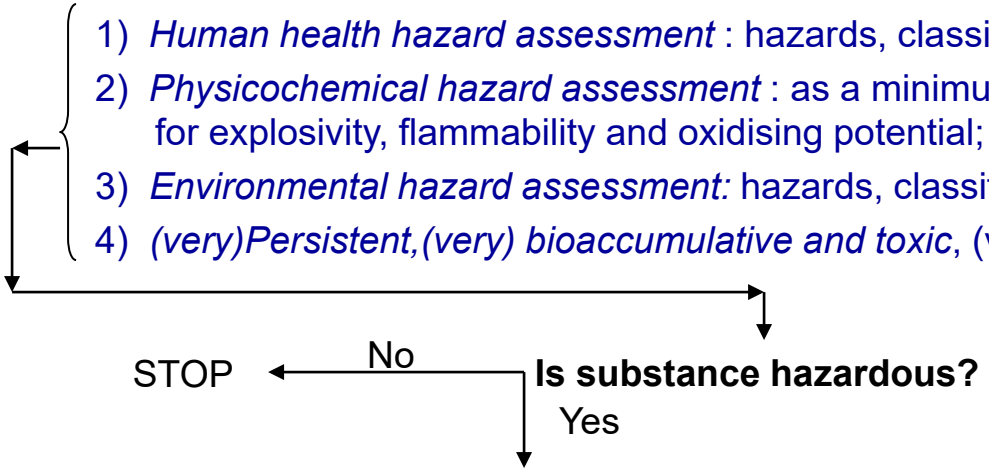
CHEMICAL SAFETY REPORT (CSR)

CSR is required if the registrant manufactures or imports a substance in quantities of 10 tonnes or more per year

CSR is the documentation of the registrant's chemical safety assessment (CSA)

Stages of CSA:

- **Hazard assessment:**
  1) *Human health hazard assessment* : hazards, classification & labelling, DNEL
  2) *Physicochemical hazard assessment* : as a minimum, the potential effects to human health for explosivity, flammability and oxidising potential;
  3) *Environmental hazard assessment:* hazards, classification & labelling, PNEC ;
  4) *(very)Persistent,(very) bioaccumulative and toxic*, (v)P(v)BT



- **Exposure assessment:**
  - *Generation of exposure scenario(s)*(ES): OC& RMM for all identified uses and stages in the life cycle;
  - *Exposure estimation*: level of exposure;

- **Risk characterisation:** for each ES compare DNEL, PNEC to exposure and assess the severity of physicochemical adverse effects

RISK CHARACTERISATION

Source: Anniversary stamp for the Royal Shakespeare Company
http://virtualstampclub.com/lloydblog/?p=1741

To be, or not to be < 1, that is the question in chemical risk assessment

RCR = Exposure/DNEL< 1, for humans

RCR = PEC/PNEC < 1, for environment

REACH PROCESSES

EVALUATION

There are three types of evaluation :

- **Compliance check of registration dossiers :** ECHA checks at least some dossiers per each tonnage band

- **Examination of testing proposals** submitted by registrants – third party consultation is made to avoid unnecessary testing

- **Substance evaluation**

MS evaluate certain substances to clarify whether their use poses a risk. The objective is to request further information from the registrants of the substance to verify the suspected concern, if necessary.

In cooperation with MS, ECHA defines risk-based criteria and selects substances to be evaluated and lists them in the Community rolling action plan (CoRAP). An evaluating MS will be designated for each substance.

The substance evaluation assesses all registration dossiers from all registrants specific to the same substance.

REACH PROCESSES

EVALUATION

Follow-up actions to substance evaluation if, after review of the available and new data, the evaluating MS considers that the use of the substance poses a risk:

- A proposal for harmonised classification and labelling for carcinogenic, mutagenic or toxic to reproductions, respiratory sensitisers or other effects.

- A proposal to identify the substance as a substance of very high concern (SVHC).

- A proposal to restrict the substance.

- Actions outside the scope of REACH such as a proposal for EU-wide occupational exposure limits, national measures or voluntary industry actions.

REACH PROCESSES

AUTHORISATION

The route to authorisation starts when a MS or ECHA, at the request of the Commission, proposes a substance to be identified as a **substance of very high concern (SVHC),** defined as:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B in accordance with CLP Regulation (CMR substances)

- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH (Annex XIII)

- Substances identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause an equivalent level of concern as with CMR or PBT/vPvB substances.

AUTHORISATION

Primarily SVHC are included in the **Candidate List**, for eventual inclusion in the Authorisation List.

ECHA prioritizes substances in the Candidate List and sends recommendations to the Commission for the inclusion in the **Authorisation List.**

The Commission decides on the inclusion and establishes:
-**The Sunset Date:** after which putting on the market or using the substance is prohibited without an authorisation
- **Latest application** – latest date when registrants can apply to use the substance after the Sunset Day
- **Uses exempted**

AUTHORISATION

Application for authorisation

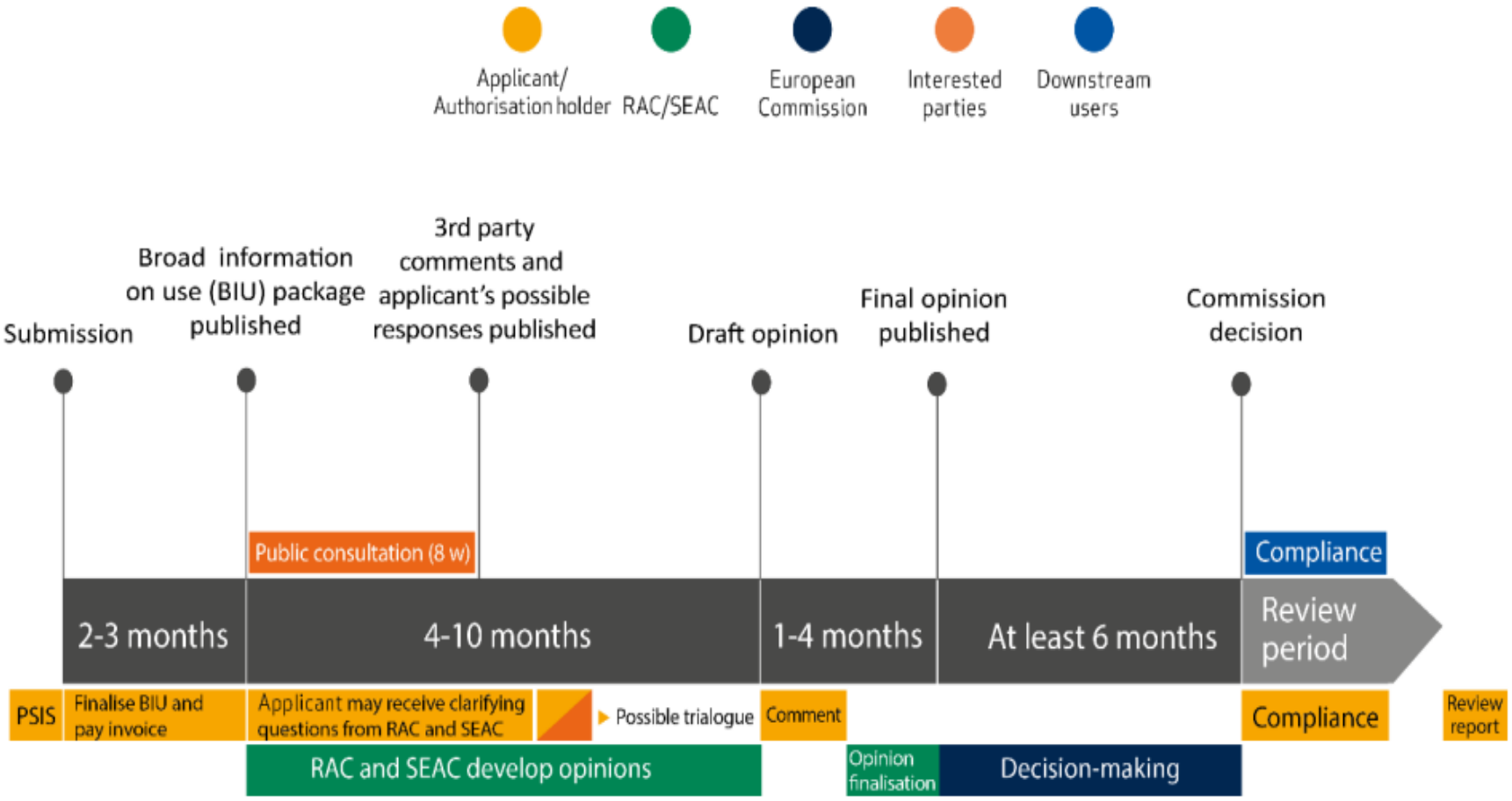
Manufacturers, importers or downstream users application includes:
- Chemical Safety Report
- Analysis of possible alternatives
- Substitution plan if suitable alternative exist
- A socio- economic analysis, if needed

Decision on granting the authorisation

RAC & SEAC make draft opinions that are subject to public consultation and applicant's comments before the final opinion is sent to the Commission who decides on granting the authorisation for certain use.

Manufacturers and importers have to put the authorisation number on the label of the substance and downstream users have to notify ECHA that they use such a substance.

Indicative timeline for an application for authorisation



https://echa.europa.eu/documents/10162/13637/apply_for_authorisation_en.pdf/bd1c2842-4c90-7a1a-3e48-f5eaf3954676

REACH PROCESSES

RESTRICTION

MS or ECHA (by request of the Commission) can propose restrictions if they consider that risks need to be address at EU level.

RAC & SEAC formulate opinions on the restriction proposal and the Forum of MS advice on the enforceability of the restriction.

The Commission decides on the restriction and in case of approval it updates the Annex XVII of REACH

RESTRICTION

Examples of restrictions in REACH Annex XVII

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
1. Polychlorinated terphenyls (PCTs)	Shall not be placed on the market, or used: — as substances, — in mixtures, including waste oils, or in equipment, in concentrations greater than 50 mg/kg (0,005 % by weight).
2. Chloroethene (vinyl chloride) CAS No 75-01-4 EC No 200-831-0	Shall not be used as propellant in aerosols for any use. Aerosols dispensers containing the substance as propellant shall not be placed on the market.

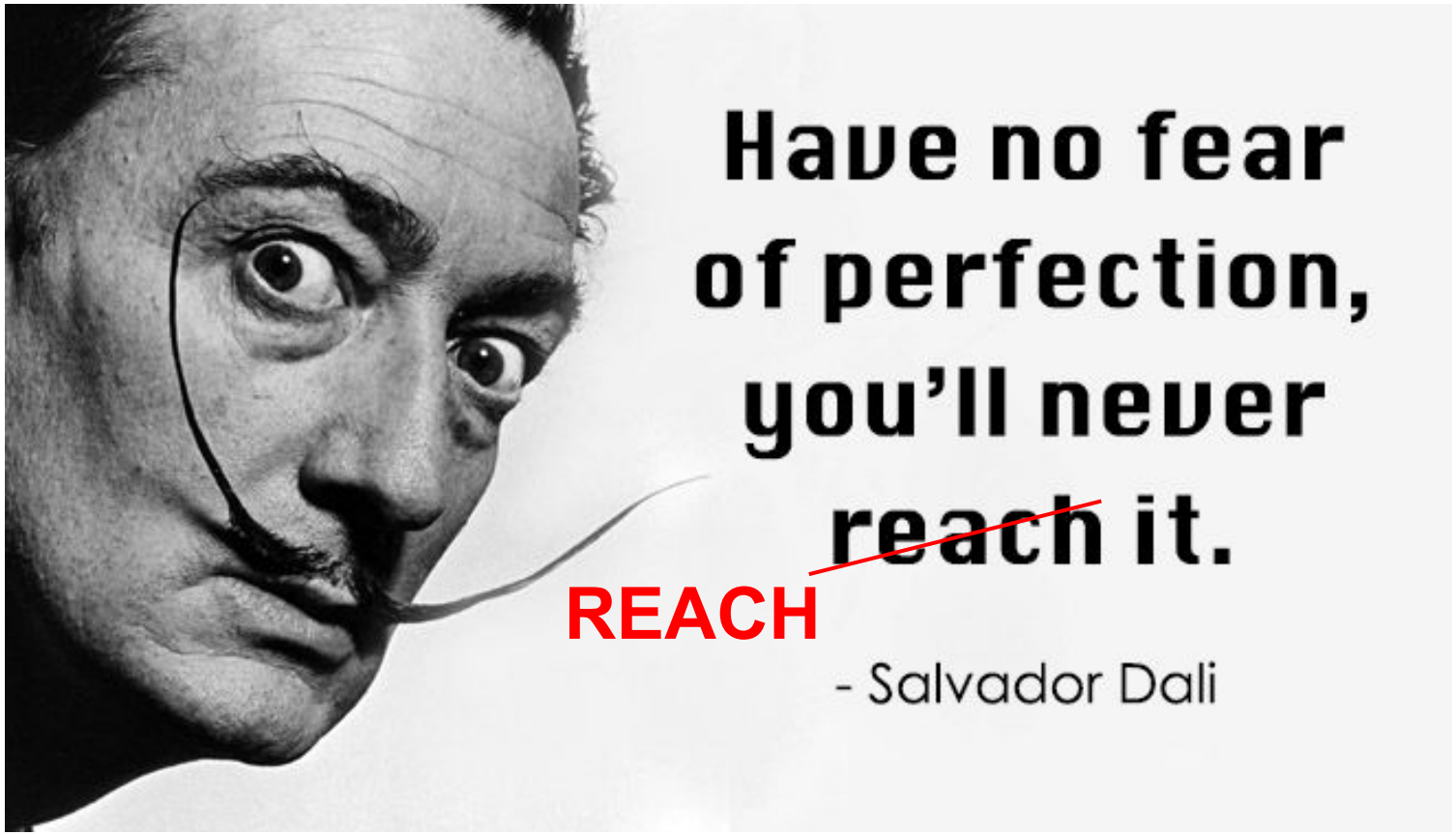
REACH ACTORS

Manufacturer/Importer/OR	Supplier	User
-Register (all docs and duties) -Inform DU on safe use (CSR, SDS) -Update information registered -Provide data requested by ECHA MSC for substance evaluation -Keep info for at least 10 year after they stopped manufacturing/importing -May apply for authorisation	-Classify & label substances -Communicate relevant information to DU -Apply for authorisation , if needed -Put the authorisation number on SDS -provide DU with SDS	-Communicate up the supply chain -Implement safe uses as in SDS/e-SDS (from10t) -If DU is not covered by supplier's (e)SDS, then: -Informs supplier to include DU use in "identified uses", CSA/CSR (if needed) Or: -Changes supplier to one that covers DU uses Or : -Notifies ECHA and prepare its own documents -Sends ECHA DU Report Or : -Takes other measures :align RMM &OC to SDS/ substitutes etc) -May apply for authorisation instead of the supplier immediately above it in the supply chain

Abbreviations

- **Chesar** (Chemical safety assessment and reporting tool) help registrants with CSA and CSRCSR
- **CSA-** Chemical Safety assessment
- **CSR** – Chemical safety report
- **DNEL** derived no-effect level(s). The DNEL is regarded as an exposure level below which an adverse effect will not not occur (for a particular route and duration of exposure)
- **DU**- downstream User
- **ECHA**- European Chemicals Agenncy
- **ES**- Exposure scenario
- **EUCLID** - International Uniform Chemical Information Database records, stores, maintains and exchanges data on intrinsic and hazard properties of chemicals
- **CoRAP** - Community rolling action plan
- **SVHC**- Substances of very high concern (see REACH Art 57)
- **OC** – operational conditions
- **OR** -Only Representative – representing non-EU companies
- **PEC**- Predicted environmental concentration
- **PNEC**- Predicted no-effect concentration
- **RAC**- Risk Assessment Committee – a structure o ECHA
- **RCR** – Risk Characterization Ratio
- **REACH IT-** tool for registering substances
- **RMM-** Risk management measures
- **SDS**- Safety data sheet
- **SEAC**- Socio-Economic Analysis Committee – a structure of ECHA
- **SIEF**- Substance Information exchange Forum a system to help registrants share information, is supported by REACH-IT, is lead by a Lead registrant

CONOSCEDE FINAL FUN PAGE



Thank you!

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