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# REACH

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**R**egistration, **E**valuation, **A**uthorization  
and Restriction of **CH**emicals.

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# What is REACH?

- REACH is the Regulation for **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemicals.
- It entered into force on 1st June 2007 to streamline and improve the former legislative framework on chemicals of the European Union (EU). REACH places greater responsibility on industry to manage the risks that chemicals may pose to the health and the environment.
- In principle **REACH applies to all chemicals**: not only chemicals used in industrial processes but also in our day-to-day life, for example in cleaning products, paints as well as in articles such as clothes, furniture and electrical appliances.

# Why REACH?

- REACH replaces about **40** pieces of legislation with a streamlined and improved Regulation.
- Other legislation regulating chemicals (e.g. on cosmetics, detergents) or related legislation (e.g. on health and safety of workers handling chemicals, product safety, construction products) not replaced by REACH will continue to apply.
- REACH has been designed not to overlap or conflict with the other chemical legislation.

# Legislation

- **REGULATION (EC) No 1907/2006**
- This is the REACH regulation which entered into force on 1<sup>st</sup> June 2007.
- **DIRECTIVE 2006/121/EC**
- amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency

# Objective

The aims of REACH are to:

- Improve the protection of human health and the environment from the risks that can be posed by chemicals
- Enhance the competitiveness of the EU chemicals industry, a key sector for the economy of the EU
- Promote alternative methods for the assessment of hazards of substances
- Ensure the free circulation of substances on the internal market of the European Union

# How Does It Work?

- **Manufacturers and importers** are obliged to register substances they produce or import in quantities over **1 tonne per year**. The registration requirement applies to substances on their own, in preparations and in articles under special conditions (intentional release). Failure to register means that the substance cannot be manufactured, imported or used in the EU market. Substances have to be registered.
- Substances are individual chemicals such as sulphuric acid, hydrochloric acid, lactic acid etc.
- Preparations do not have to be registered. A preparation is a mixture of chemicals.
- **BUT!!** – the substances present in a preparation have to be registered.
- **NO FREE RIDERS** allowed – you have to ensure that the supplier has registered the substance

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# REACH Applies to Substances

- Generally, a 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
- The following are exempt from registration.
  - Radioactive substances
  - Non-isolated Intermediates
  - Waste
  - Chemical/Biological Weapons
  - Titles II, V, VI & VII do not apply to medicines
  - Food Additives
  - More details 1907/2006 L396/48

# 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

# Pre-Registration – Date Has Passed

- It is estimated that there are around 30,000 substances on the European Market in quantities of 1 tonne or more per year. Registering all of these at once would be a huge task for both industry and regulators. To overcome this, the registration of those substances already being manufactured or supplied is to take place in three phases. These phases are spread over 11 years. To benefit from these provisions manufacturers or suppliers should pre-register their substances between 1st June to 30th November 2008.
- Once pre-registered the European Chemicals Agency will identify who is intending to register the same substance and put them in contact with each other. The potential registrants can then come together and form a 'Substance Information Exchange Forum' (SIEF) where they can negotiate sharing their available data and the costs of any generating any new data.

# How does REACH work?

- REACH makes industry bear most responsibilities to manage the risks posed by chemicals and provide appropriate safety information to their users.
- In parallel, it foresees that the European Union can take additional measures on highly dangerous substances, where there is a need for complementing action at EU level.
- REACH also creates the [European Chemicals Agency](#) (ECHA) with a central coordination and implementation role in the overall process.
- **All manufacturers and importers of chemicals** must identify and manage risks linked to the substances they manufacture and market. For substances produced or imported in quantities of **1 tonne or more per year per company**, manufacturers and importers need to demonstrate that they have appropriately done so by means of a **registration dossier**, which shall be submitted to the Agency.
- Once the registration dossier has been received, the Agency may check that it is compliant with the Regulation and shall evaluate testing proposals to ensure that the assessment of the chemical substances will not result in unnecessary testing, especially on animals.
- Where appropriate, authorities may also select substances for a broader substance evaluation to further investigate substances of concern.

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# Registration Dossier Contents

- Identity of Manufacturer or Importer
- Identity of Substance
- Information on the manufacture and use of substance
- Classification & Labelling of substance
- Guidance on safe use of substance
- Study summaries re toxicology & ecotoxicity
- Details of which information has been reviewed by an assessor.
- Proposals for testing
- Exposure information (substances 1 – 10 tonnes)
- Chemical Safety Report as per Annex I

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# ECHA

- European Chemical Agency
- Website – <http://ec.europa.eu/echa>
- The Agency, located in Helsinki, Finland manages the registration, evaluation, authorisation and restriction processes for chemical substances to ensure consistency across the European Union.
- At present the agency employs over 400 staff directly, with a yearly spend of > €80 million, of which ~ 50% is generated through fees.

# REACH – Costs

- Fees for registration, authorisation & PPORD
- Registration fees will grow with tonnage
- SMEs & joint registrations will pay less
- Below 10 tons registration is free for complete dossiers
- For dossiers, some testing can cost €250,000+
- SIEFs can be used to share costs

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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

# “Phase-in Substances”

- Such substances which were already being manufactured or placed on the market before the entry into force of the REACH Regulation are called “**phase-in substances**”, because they are being subjected to the registration system in different phases over time, rather than immediately in one go.
- **A precondition is that the phase-in substance is being pre-registered within between the 1 st June 2008 and the 1 st December 2008.**
- Phase-in substances are substances which fall under at least one of the following criteria:
- *The substance is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) (Article 3 (20)(a)).* The EINECS list contains, in principle, all substances on the Community market on 18 September 1981. These are the so-called “existing substances”. The full and exhaustive list is accessible at <http://ecb.jrc.it/esis/>. Note that the list has been “frozen” and no more substances can be added to it or removed from it. Note that the list has been “frozen” and no more substances can be added to it or removed from it.
- The substance was manufactured in any of the current Member States of the EU except (Bulgaria and Romania), at least once after 31 May 1992, without being placed on the EU market by the manufacturer or importer, provided that the manufacturer or importer has documentary evidence of this. Such documentary evidence can be, for example, order sheets, stock lists, or any other documents which can be undoubtedly traced back to a date after 31 May 1992. If the substance was placed on the market, it would normally have been notified under Directive 67/548/EEC and in that case it will be considered as registered.
- The substance was placed on the market in any of the current Member States of the EU , or in Finland, Austria, Sweden, Estonia, Latvia, Lithuania, Malta, Slovenia, Hungary, Cyprus, Poland, the Czech Republic or the Slovak Republic before 1 June 2007 by the manufacturer or importer, and is a so-called “no-longer polymer ” (NLP). ”. A NLP is a substance which was placed on the EU market between 18 September 1981 and 31 October 1993 inclusive, was considered as notified under Article 8 (1) of the 6 th amendment of Directive 67/54/EEC (and hence did not have to be notified under that Directive), but which does not meet the REACH definition of a polymer (which is the same as the polymer definition introduced by the 7 th amendment of Directive 67/548/EEC). Also in this case, the manufacturer or importer must have documentary evidence that he placed the substance on the market in the relevant territory and that it was considered as NLP (and as such considered as notified under Article 8 (1) of the 6 th amendment). Such documentary evidence can be, for example, order sheets, stock lists, labels, safety data sheets, or any other documents which can be undoubtedly traced back to a date after 31 May 1992. between 18 September 1981 and 31 October 1993 inclusive. A non-exhaustive list of NLPs is accessible at <http://ecb.jrc.it/esis/>; note that it only serves information purposes.

# Who will REACH effect?

- The scope of the future legislation will affect not only manufacturers and importers but may also require users of chemical substances (**downstream-users**) to **provide information on their specific uses** and the safety procedures associated with that use.
- Industry as a whole could as a result face a situation where **some chemicals are withdrawn from the market** with product manufacturers having to reformulate their products.

# How does REACH work?

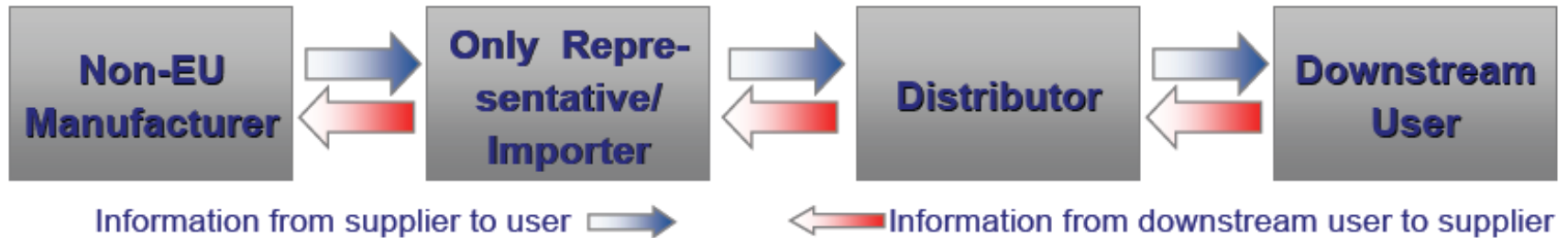
- REACH also foresees an authorisation system aiming to ensure that substances of very high concern are adequately controlled, and progressively substituted by safer substances or technologies or only used where there is an overall benefit for society of using the substance.
- These substances will be prioritised and over time included in **Annex XIV**. Once they are included, industry will have to submit applications to the Agency on authorisation for continued use of these substances. In addition, EU authorities may impose restrictions on the manufacture, use or placing on the market of substances causing an unacceptable risk to human health or the environment.
- Manufacturers and importers must provide their downstream users with the risk information they need to use the substance safely. This will be done via the classification and labelling system and Safety Data Sheets (SDS), where needed.
- Substances can be exempted from all or a part of the obligations under REACH.

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# The Supply Chain

- Manufacturer (M)
- Importer (I)
- Distributor (D)
- Downstream User (DU)
- Your company may have more than 1 role

# REACH Supply Chain



- **Manufacturer or Importer** - Registers substances and identified uses- Prepares chemical safety report (CSR), exposure scenario and risk management measures (RMM)
- **Only Representative**-Appointed by to carry out the registration and thus coequal to an importer
- **Distributor** -Up-and downstream supply chain communication
- **Downstream User** -Should follow advised RMM-Should inform supplier about use and exposure-In case of non-identified use (> 1 t/a) : registration + CSR

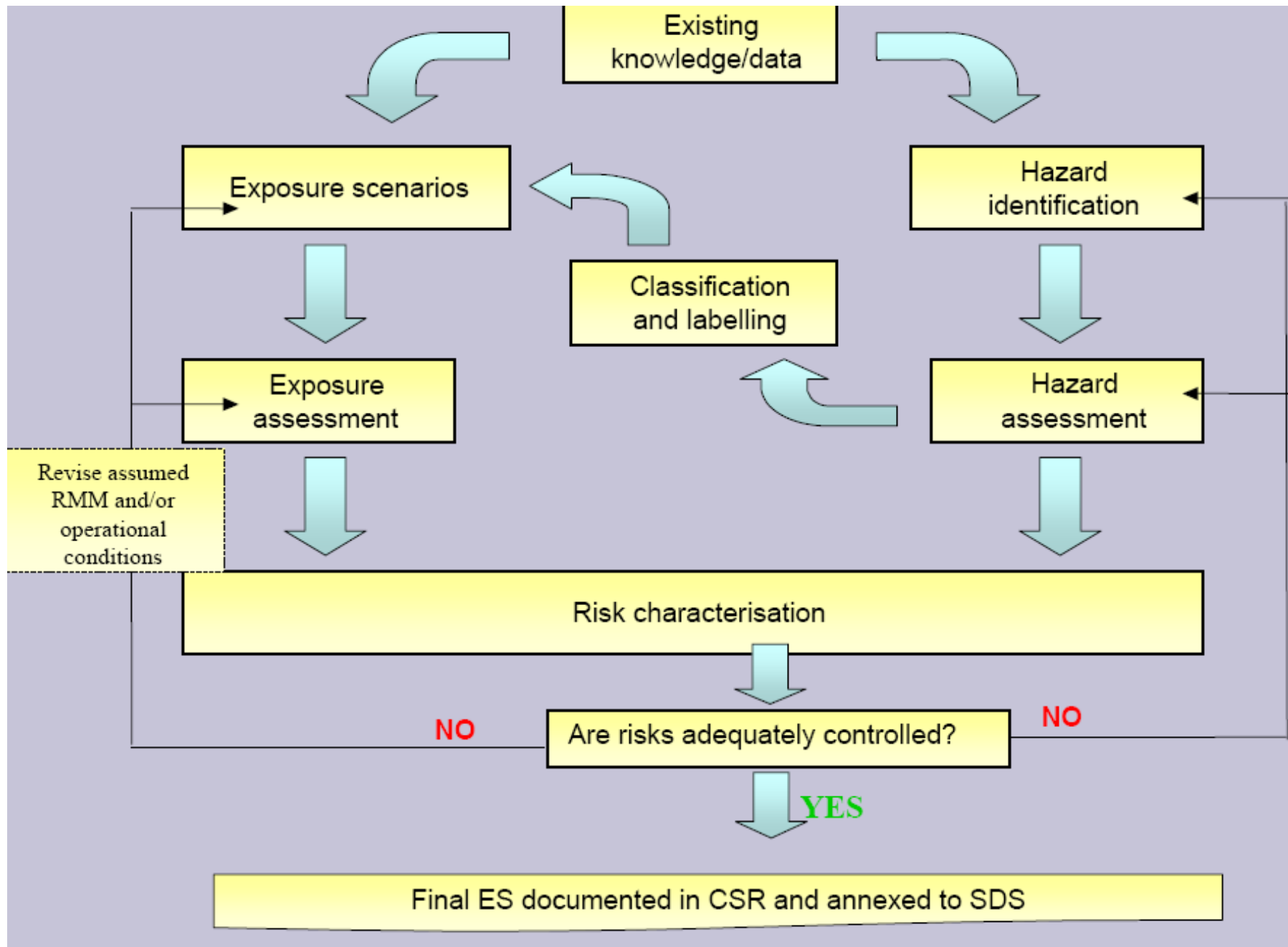
# Tools for Communication in Supply Chain

- ***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.
- ***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 for manufacture and/or each identified use
  - Specify risk management measures for each use
  - Address use identified by DU



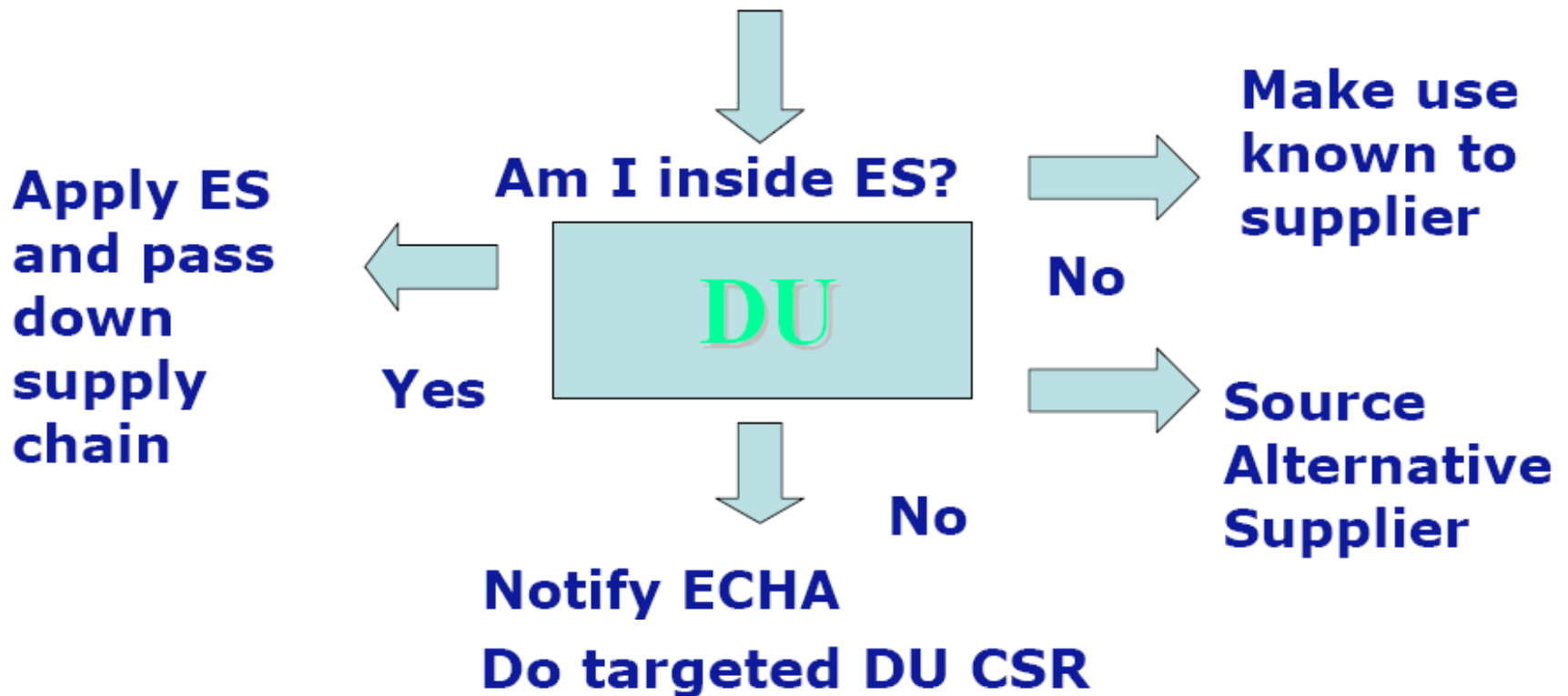
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# What must an Exposure Scenario cover?

- Manufacture (EU)
- Manufacturer / importers own use
- Identified downstream use (s)
- Entire life cycle
- Exposure of workers, consumers, environment, man via environment
- Specific to Generic Uses

# Downstream User – Am I covered by my suppliers SDS?

## SDS + Exposure Scenarios (ES)

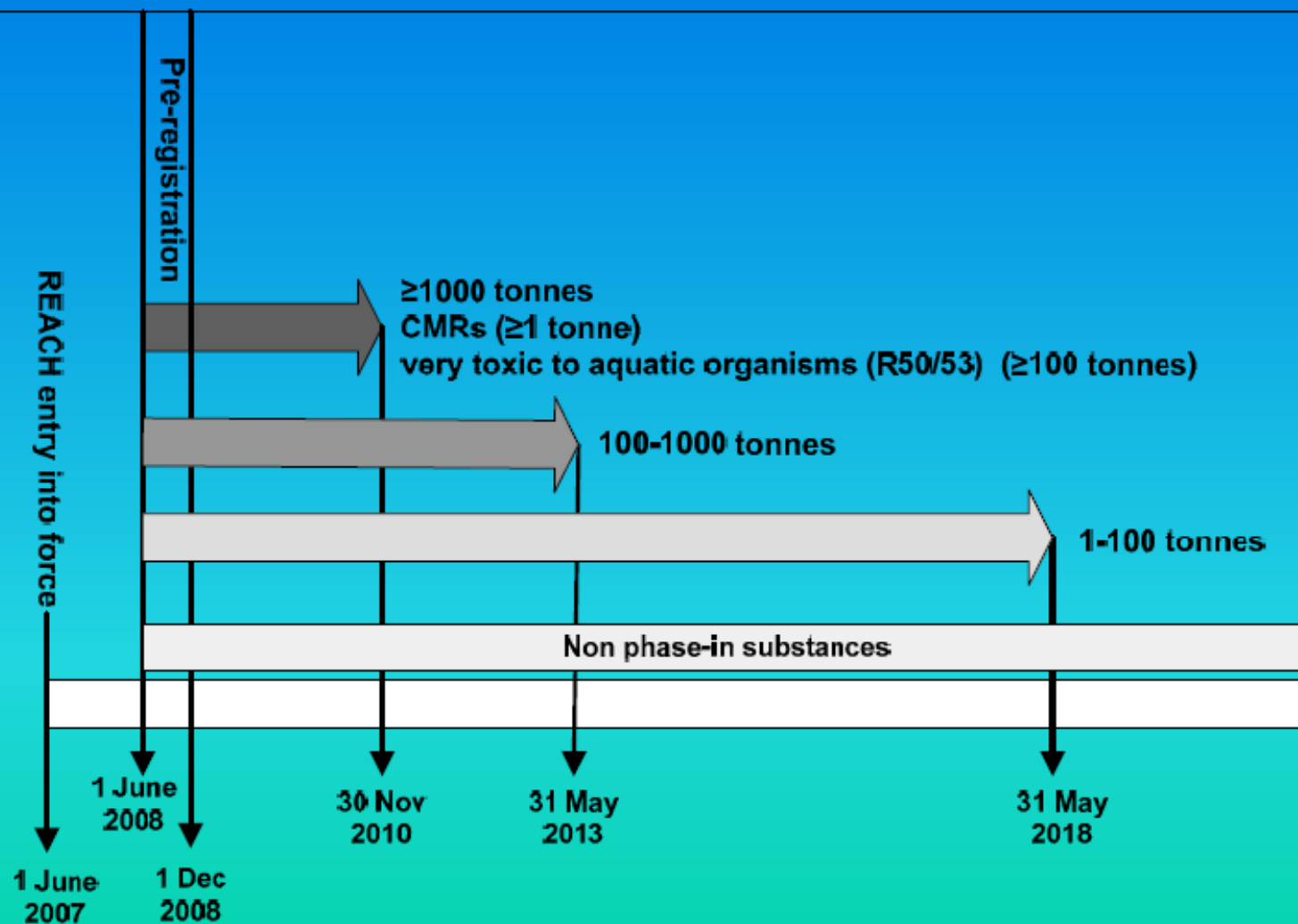


# Safety Data Sheet - Changes

- Primary tool for downstream communication
- Slight change in format
- Exposure Scenario (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'
- Now - Move to **GHS**



# Registration timeline



# Registration Timelines

- ❑ Chemicals already existing (those on EINECS or manufactured in the EU prior to entry into force of REACH) are known as 'phase-in' substances under REACH. These will be registered in three phases according to their tonnage and/or hazardous properties.
  - ❑ Phase 1 – substances supplied at  $\geq 1,000$  tonnes per year; substances classified under CHIP as very toxic to aquatic organisms supplied at  $\geq 100$  tonnes per year; substance classified under CHIP as Category 1 or 2 carcinogens, mutagens or reproductive toxicants supplied at  $\geq 1$  tonne per year; substances classified as very toxic to aquatic organisms must be registered in the first three years (by 1 December 2010).
  - ❑ Phase 2 - substances supplied at  $\geq 100$  tonnes per year must be registered in the first six years (by 1 June 2013).
  - ❑ Phase 3 - substances supplied at  $\geq 1$  tonne per year must be registered in the first 11 years (by 1 June 2018).
  
- ❑ A substance can be registered at any time prior to these deadlines.

# REACH Timeline

<b>1 June 2007:</b>	REACH entered into force
<b>1 June 2007:</b>	Provisions entered into force regarding substances and preparations that do not require a safety data sheet, down the supply chain
<b>1 June 2007</b>	Provisions regarding the provision of REACH specification Safety Data Sheets down the supply chain entered into force
<b>1 June 2008:</b>	European Chemicals Agency becomes operational
<b>1 June 2008:</b>	Pre-registration of phase-in substances begins, including for substances intended to be released from articles (ends 1 December 2008)
<b>1 June 2008:</b>	Registration dossiers may be submitted for phase-in substances from this point onwards
<b>1 June 2008:</b>	From this point onwards, new substances need to be registered before they be imported or placed on the market
<b>1 December 2008:</b>	End of pre-registration period for phase-in substances ends

# REACH Timeline Continued

<b>1 June 2009:</b>	European Chemicals Agency will have prepared and published a list of candidate substances to which authorisation may apply
<b>30 November 2010:</b>	Deadline for the registration of all phase-in substances manufactured or imported above 1,000 tonnes per year as well as CMR (cat 1 or 2) substances above 1 tonne per year* or substances classified as very toxic to aquatic organisms (R50-R53) above 100 tonnes*. The classification referred to here is that of the current system (under the framework of Directive 67/548/EEC) which will be superseded, in due course, by the Globally Harmonised System of classification and labelling (GHS)
<b>1 December 2010:</b>	From this point onwards, the obligation to notify the European Chemicals Agency with information necessary for it to compile a classification and labelling inventory, applies for substances which meet the criteria for classification as dangerous. This obligation applies to all new and phase-in substances regardless of quantity
<b>1 June 2011:</b>	Articles containing substances of high concern will now require registration and notification six months after the identification of these substances as being of concern
<b>31 May 2013:</b>	Deadline for the registration of all phase in substances manufactured or imported above 100 tonnes per year*
<b>1 June 2018:</b>	Deadline for the registration of all phase-in substances above 1 tonne per year*
* Quantities are per EU manufacturer and/or importer to the EU	

# Exposure scenarios

- Exposure scenarios must be prepared when a substance is manufactured or imported in quantities of **10 tonnes** per year and above and classified as dangerous or as **PBT/vPvB**.
- An exposure scenario is a set of conditions that describe how a substance (as such, in a preparation or in an article) is manufactured or used during its life-cycle and how the manufacturer or importer or downstream user controls or recommends controlling exposure of humans and the environment.
- An exposure scenario must include the appropriate risk management measures and operational conditions that, when properly implemented, ensure that the risks from the uses of the substance are adequately controlled.

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# Customers

- Raw Materials used in products purchased from Schlotter have been pre-registered.
- May be some communication re new Safety Data Sheets and Use of Products between Customers and Schlotter.
- Product use is communicated via generic uses, so minimal information is released into the public domain.

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# Current Status

- Schlotter has communicated with all suppliers and been assured that all products will be registered.

# SVHC

- **SVHC = substances of very high concern**

In general terms, SVHC are substances that have hazards with serious consequences, e.g., they cause cancer, or they have other hazardous properties and/or remain in the environment for a long time with their amounts in animals gradually building up.

- **REACH – “A = authorization”**

- Substances of very high concern will be gradually included in Annex XIV of the REACH Regulation. Once included in that Annex, they cannot be placed on the market or used after a date to be set (the so-called “sunset date”) unless the company is granted an authorisation.

# SVHC Definition

- The criteria in REACH, Article 57 for these SVHC are:
- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1 or 2 in accordance with Directive 67/548/EEC;
- Substances which are persistent, bio-accumulative and toxic (PBT) in accordance with the criteria set out in Annex XIII of the REACH Regulation;
- Substances which are very persistent and very bio-accumulative (vPvB) in accordance with the criteria set out in Annex XIII of the REACH Regulation;
- Substances giving rise to an equivalent level of concern to substances meeting the above criteria. Such substances may have endocrine disrupting properties or have properties, that although not meeting the criteria for being a CMR, PBT or vPvB, there is scientific evidence of probable serious effects to human health or the environment. Such substances will be identified on a case-by-case basis.

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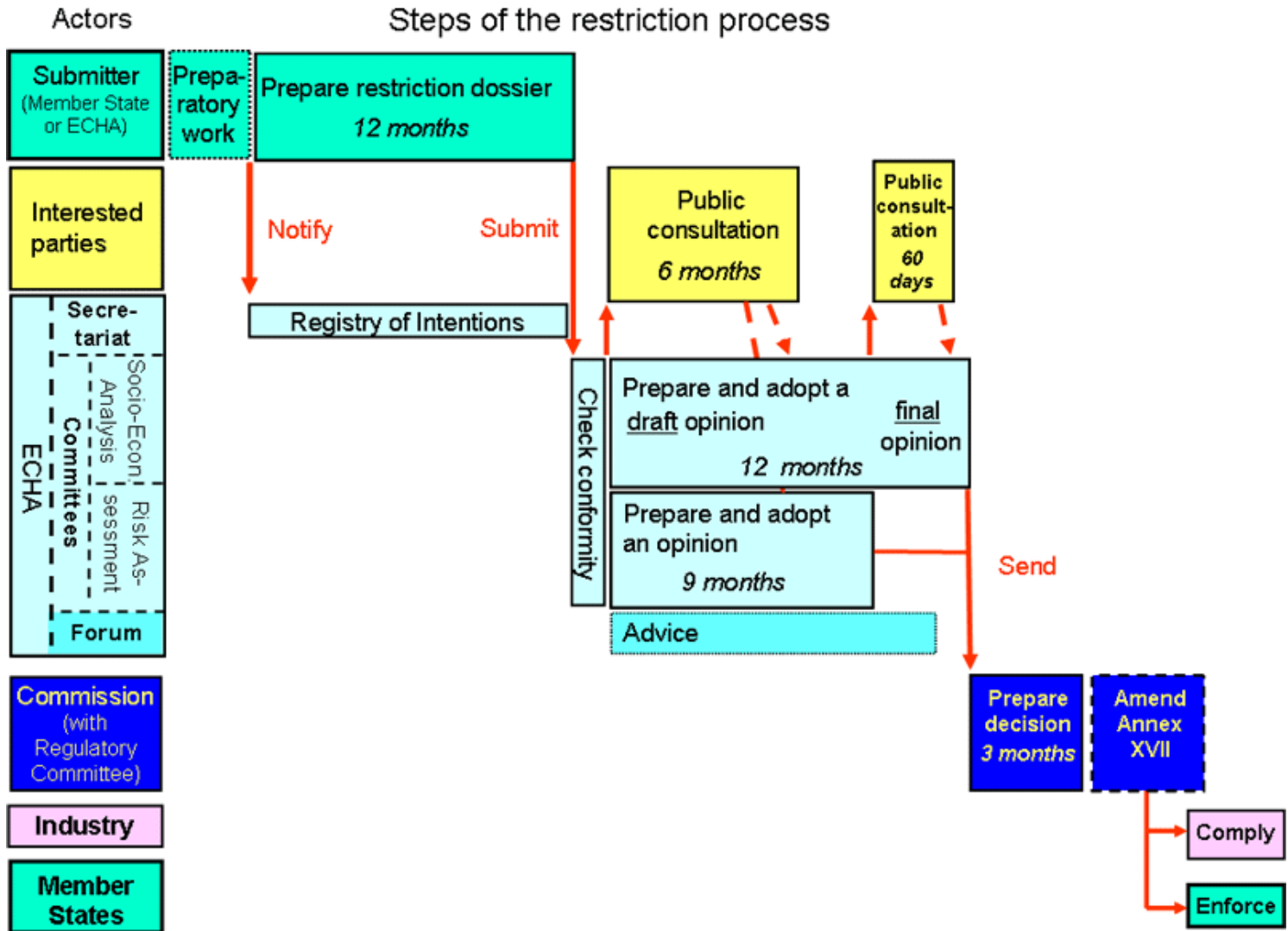
# Current Restrictions

- The current restrictions are listed in amendments to **Annex XVII** of REACH.
- **Example: COMMISSION REGULATION (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII**
- Nickel is listed as restricted – how?

# Nickel Restriction

- 1. Shall not be used:
  - (a) in any post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than  $0,2 \mu\text{g}/\text{cm}^2 / \text{week}$  (migration limit);
  - (b) in articles intended to come into direct and prolonged contact with the skin such as: — earrings, — necklaces, bracelets and chains, anklets, finger rings, — wrist-watch cases, watch straps and tighteners, — rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments, if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than  $0,5 \mu\text{g}/\text{cm}^2 / \text{week}$ .
  - (c) in articles referred to in point (b) where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed  $0,5 \mu\text{g}/\text{cm}^2 / \text{week}$  for a period of at least two years of normal use of the article.
- 2. Articles which are the subject of paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph.
- 3. The standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 and 2.

# Restriction Process



# “Candidate List”

- ECHA publish a candidate list for substances which may require **authorisation** in the future.
- [http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)
- Compounds of interest for electroplaters on the candidate list are boric acid, chromic acid, sodium dichromate and several cobalt compounds.

# Authorisation Process

- **Step 1:** Identification of substances of very high concern (by authorities)
- Substances of very high concern can be identified on the basis of the criteria previously described. This will be done by Member State Competent Authorities or the Agency (on behalf of the European Commission) by preparing a dossier in accordance with Annex XV. Interested parties can comment on substances for which a dossier has been prepared. The outcome of this identification process is a list of identified substances, which are candidates for prioritisation (the “candidate list”).

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# Authorisation Process

- Step 2: Prioritisation process (by authorities)
- The substances on the candidate list are then prioritised to determine which ones should be subject to authorisation. Interested parties are invited to submit comments during this process. At the end of the prioritization process, the following decisions are taken: whether or not the substance will be subject to authorisation; which uses of the included substances will not need authorisation (e.g. because sufficient controls established by other legislation are already in place); the “**sunset date**” by when a substance can no more be used without authorisation.

# Authorisation Process

- Step 3: Applications for authorisation (by industry)
- Applications for authorisation need to be made within the set deadlines for each use that is not exempted from the authorisation requirement. They must include among others:
  - a chemical safety report covering risks related to those properties that caused the substance to be included in authorisation system (unless already submitted as part of the registration)
  - an analysis of possible alternative substances or technologies including, where appropriate, information on research and development foreseen or already in progress to develop such alternatives.
- Applications for authorization need to be made by individual companies, and cannot be made by industry bodies.

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# Authorisation Process

- If the analysis of alternatives reveals that there is a suitable alternative, the applicant must submit a substitution plan, explaining how he intends to replace the substance by the alternative. The suitability of available alternatives is assessed taking into account all relevant aspects, including whether the alternative results in reduction of overall risks and is technically and economically feasible.
- An applicant can include a socio-economic analysis in his application, but in cases where he is not able to demonstrate adequate control of risks and where no suitable alternative exists, he needs to include one in his application.
- A fee has to be paid for each application.
- For all applications, the Agency will provide expert opinions. The applicant can comment on these opinions.

# Authorisation Process

- **Step 4: Granting of authorisations (by the European Commission)**
- Authorisations will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled. The “adequate control route” does not apply for substances for which it is not possible to determine thresholds and substances with PBT or vPvB properties.
- If the risk is not adequately controlled, an **authorisation may still be granted if it is proven that the socio-economic benefits outweigh the risks** and there are no suitable alternative substances or technologies.
- Downstream users may only use such substances for uses which have been authorised.
- For this they must either:
  - obtain the substance from a company that was granted an authorisation for that use. They must stay within the conditions of that authorisation. Such downstream users must notify the Agency that they are using an authorised substance.
  - apply themselves for authorisations for their own uses.

# Authorization Fee Structure

Fees for applications for an authorisation under Article 62 of Regulation (EC) No 1907/2006

Table 1  
Standard fees

Base fee	EUR 50 000
Additional fee per substance	EUR 10 000
Additional fee per use	EUR 10 000
Additional fee per applicant	Additional applicant is not an SME: EUR 37 500
	Additional applicant is a medium enterprise: EUR 30 000
	Additional applicant is a small enterprise: EUR 18 750
	Additional applicant is a micro enterprise: EUR 5 625

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# Useful Websites

- ECHA

- [http://ec.europa.eu/echa/home\\_en.html](http://ec.europa.eu/echa/home_en.html)

- Authorisation

- [http://guidance.echa.europa.eu/authorisation\\_en.htm](http://guidance.echa.europa.eu/authorisation_en.htm)

- HSE

- <http://www.hse.gov.uk/reach/index.htm>

- HSA

- <http://www.hsa.ie/eng/Sectors/Chemicals/REACH/>

# Acronyms

- CA Competent Authority
- CMR Carcinogen, mutagen or reproductive toxicant
- Concentration (environment)
- CSA Chemical Safety Assessment
- CSR Chemical Safety Report
- DNEL Derived NoEffect
- DU Downstream user
- E Ch A European Chemicals Agency
- EINECS European Inventory of New and
- ES Exposure Scenario
- Existing Chemical Substances
- GLP Good Laboratory Practice
- HSE Health and Safety Executive
- IUCLID International Uniform Chemical Information Database
- Level (human health)
- M/I Manufacturer / Importer
- PBT – Bio accumulative & Toxic
- PBT Persistent, Bioaccumulative and Toxic
- PNEC Predicted NoEffect
- PPORD Product and Process Orientated
- QSAR Quantitative StructureActivity
- REACH Registration, Evaluation and Authorisation of Chemicals  
CMR – carcinogenic, mutagenic or toxic to reproduction.
- Relationships
- Research and Development
- RIP REACH Implementation Project
- SIEF Substance Information Exchange Forum
- SVHC Substance of Very High Concern
- T/yr Tonnes per year
- TGD Technical Guidance Document
- vPvB – very Persistent and very Bioaccumulative
- VPVB Very Persistent and Very Bioaccumulative

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# New CLP (GHS) Regulations

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## Classification, Packaging & Labelling

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# Summary

- The CLP Regulation is the new EU legislation on Classification, Labelling and Packaging of substances and mixtures. It integrates the classification criteria of the United Nations Globally Harmonised System (GHS) into EU law. The CLP Regulation will gradually replace the Dangerous Substances Directive (DSD) and the Dangerous Preparations Directive (DPD).

# What is CLP?

- **CLP = Labels + Safety Data Sheets**
- "CLP" or "the CLP Regulation" stands for Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH). It implements the 2nd edition of the United Nations Globally Harmonised System of classification and labelling of chemicals (GHS) into EU law. Commission Regulation (EU) No 453/2010 of 20 May 2010 contains further amendments regarding Safety Datasheets.

# What is GHS?

- ❑ **GHS = DIFFERENT LABEL + DIFFERENT SAFETY DATA SHEET**
- ❑ GHS stands for the **Globally Harmonised System** of classification and labelling of chemicals. It provides a basis for uniform physical, environmental, health and safety information on hazardous chemicals at global level through the harmonisation of the classification criteria, labelling rules and guidance on the preparation of Safety Data Sheets.
- ❑ The GHS is developed and maintained at United Nations level with the aim of avoiding different hazard information requirements on physical, health and environmental hazards for the same chemicals around the world. In addition, it also aims to facilitate trade: by applying GHS across different countries, it will no longer be necessary for an exported chemical to be reclassified and relabelled in order to comply with different classification criteria, labelling rules and Safety Data Sheet requirements of the importing country.
- ❑ For further information on the development of the UN GHS, please see [http://www.unece.org/trans/danger/publi/ghs/histback\\_e.html](http://www.unece.org/trans/danger/publi/ghs/histback_e.html).
- ❑ **This will REPLACE CURRENT LABELS + SAFETY DATA SHEETS**

# Different Between GHS & CLP?

- The GHS was implemented through Community legislation in the form of **Regulation (EC) No. 1272/2008** on classification, labelling and packaging of substances and mixtures (CLP Regulation) which is legally binding and directly applicable in the Member States of the EU, whereas GHS is not legally binding.
- GHS and CLP are not identical because CLP is also based on the old EU legislation on classification and labelling, i.e. the Dangerous Substances Directive 67/548/EEC (DSD) and the Dangerous Preparations Directive 1999/45/EC (DPD).
- In addition, and based on the so-called UN GHS “building block approach”, CLP does not include all the hazard categories included for a hazard class because they were not part of DSD, e.g. category 4 of the hazard class flammable liquids, or category 3 (mild irritant) of the hazard class skin corrosion/irritation. CLP includes special labelling and packaging rules that are not part of the UN GHS, but which were brought over from the DSD and DPD, e.g. the rules on small packaging (CLP Article 29), on supplemental information for certain mixtures (Part 2 of Annex II to CLP) and for the provision of child-resistant fastenings or tactile warnings. Also, it includes rules for the situation when a substance is both covered by CLP and by transport legislation (CLP Article 33)..
- It should be noted that in contrast to the UN GHS, CLP does not include specific rules on Safety Data Sheets as they are already regulated by REACH, through its Article 31 and Annex II.

# Are there changes to Transport Regulations?

- **No.**
- Directive 2008/68/EC on the inland transport of dangerous goods which shall have been transposed by Member States into national law by 30 June 2009 includes neither references to CLP nor to the previous legislation on classification and labelling. CLP Article 1(6) states "Save where Article 33 applies this Regulation shall not apply to the transport of dangerous goods by air, sea, road, rail or inland waterways." Accordingly, CLP does not change the transport legislation. However, CLP lays down in Article 33 specific rules for labelling of outer packaging and single packaging which are transported.

# Deadlines for Implementation

- For classified substances and mixtures you must provide labels that comply with the CLP Regulation by 1 December 2010 and by 1 June 2015, respectively. Please note that in case you have already classified, labelled and packaged a substance or mixture according to CLP before the relevant deadline, only the CLP label shall appear, but not the DSD or DPD label, respectively.
- Extended deadlines for re-labelling and re-packaging are granted in case substances or mixtures are already placed on the market before the relevant deadlines: the re-labelling and re-packaging of substances and mixtures, which are already in the supply chain ('on-the-shelves') on the mandatory compliance dates, may be postponed until 1 December 2012 and 1 June 2017 respectively. The additional two years are granted in order to facilitate the move from the existing classification, labelling and packaging system to the new one, especially for those products with a longer shelf-life.

# Timelines

## January 20th 2009

- EU-GHS effective for all EU member states
- Classification, labeling and packaging of substances and mixtures according to EU-GHS is allowed

## December 1st 2010

- All substances must be classified and labeled in accordance with EU-GHS criteria

## Start transition period I **December 1st 2010 – December 1st 2012**

- Substances already placed on the market (with the old labeling and packaging) are permitted to be sold prior December 1st 2012

## June 1st 2015

- All mixtures must be classified and labeled in accordance with EU-GHS criteria

## Start transition period II **June 1st 2015 – June 2017**

- Mixtures already placed on the market (with the old labeling and packaging) are permitted to be sold prior June 1st 2017

# Key Dates

CLP Obligation	Scope	Key Dates
<b>Obligation to classify, label and package substances (Article 4)</b>	Substances placed on to the European Market (Article 4.1) Substances that are subject to registration or notification under REACH (Article 4.2)	The obligation to classify substances in line with CLP applies <b>from 1 December 2010</b> (Article 62)
<b>Obligation to notify the Agency (Article 40)</b>	Substances that are subject to registration under REACH and are placed on the market on or after 1 December 2010 (Article 39(a))  Substances classified as hazardous and which are placed on the market either on their own or in mixtures above specified concentration limits, which result in the classification of the mixture as hazardous (Article 39(b))	Substances placed on the market on or after <b>1 December 2010*</b> must be notified within <b>1 month</b> after being placed on the market (Article 40)  This means that the first notification deadline will be <b>3 January 2011</b>
<b>Obligation to classify, label and package mixtures (Article 4)</b>	Mixtures placed on European Market (Article 4.1)	The obligation to classify mixtures in line with CLP applies from <b>1 June 2015</b> (Article 62)

# CLP Timeline

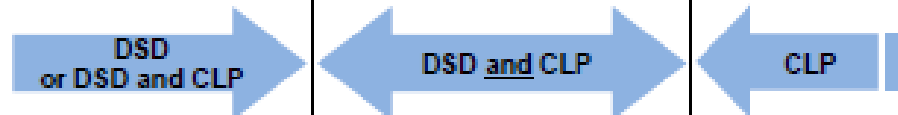
## CLP Timeline for Substances & Mixtures

1 December 2010

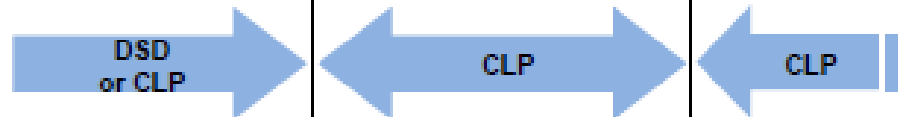
1 June 2015

### SUBSTANCES

Classification



Labelling



### MIXTURES

Classification



Labelling



Note :

*For products already on the market ("on the shelf") prior to the labelling deadline, there is an extension of 2 years before the labelling provisions are enforced. After this extension, products will have to be withdrawn from the market, relabelled and repackaged.*

# Changes to Labels

- ❑ Three main types of hazards have been defined: the **physical hazards**, the **health hazards** and the **environmental hazards**.
- ❑ These are divided into **hazard classes defined by the nature of:**
  - the physical hazard (e.g. Explosives, Self-reactive substances/  
mixtures),
  - the health hazard (e.g. Acute toxicity, Germ cell mutagenicity)
  - the environmental hazard (e.g. Hazardous to the aquatic environment, acute)

# Goodbye R & S phrases

- Equivalent to the former R-phrases are the **H-statements** (e.g. H200, H201). These are the **hazard statements** which describe the nature of the hazards of a substance or mixture.
- And equivalent to the former S-phrases are the **P-statements**. These are the **precautionary statements** which describe recommended measures to minimise or prevent adverse effects.

Schloetter Company Ltd.,  
Abbey Works,  
New Road,  
Persore,  
Worcestershire,  
WR10 1BY  
England.

Sales: 01386 552331  
Tech: 01386 552333  
email: info@schloetter.co.uk

Out of hours  
Emergency Tel:  
(+44)(0)1865 407333



**DANGER**

Restricted to professional users.

**UN1463**

**CHROMIC ACID FLAKE**

CAS 1333-82-0

IDX 824-001-00-0

EC 215-807-3

Contains chromium(VI) trioxide

**P201** Obtain special instructions before use.  
**P221** Take any precaution to avoid mixing with combustibles.  
**P260** Do not breathe dust/fume/gas/mist/vapours/spray.  
**P273** Avoid release to the environment.  
**P280** Wear protective gloves/protective clothing/eye protection/face protection.  
**P281** Use personal protective equipment as required.  
**P285** In case of inadequate ventilation wear respiratory protection.  
**P308+P313** IF exposed or concerned: Get medical advice/attention.  
**P310** Immediately call a POISON CENTER or doctor/physician.  
**P314** Get medical advice/attention if you feel unwell.  
**P342+P311** If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.  
**P501a** Dispose of contents/container to metabisulphite treatment.

**H 271** May cause fire or explosion; strong oxidizer.  
**H 301** Toxic if swallowed.  
**H 311** Toxic in contact with skin.  
**H 314** Causes severe skin burns and eye damage.  
**H 317** May cause an allergic skin reaction.  
**H 330** Fatal if inhaled.  
**H 334** May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
**H 335** May cause respiratory irritation.  
**H 340** May cause genetic defects.  
**H 350** May cause cancer.  
**H 361F** Suspected of damaging fertility.  
**H 372** Causes damage to organs through prolonged or repeated exposure.  
**H 400** Very toxic to aquatic life.  
**H 410** Very toxic to aquatic life with long lasting effects.

BATCH NUMBER

201 **005 2320**

USE BY END OF













**05/12**

PRODUCT NUMBER






**163050**

NETT WEIGHT / VOLUME













**25 kg**

Label Elements Old	Hazard Classes and Categories*	Label Elements New**
<p>EXPLOSIVE</p>  <p>(R2, R3)</p>	<p>Explosives</p> <ul style="list-style-type: none"> <li>- Unstable explosives</li> <li>- Explosives, division 1.1 to 1.3</li> <li>Self-reactive substances/mixtures, types A and B</li> <li>Organic peroxides, types A and B</li> </ul>	<p>DANGER</p>  <p>H200 H201, H202, H203 H240, H241 H240, H241</p>
<p>No classification</p>	<p>Explosives, division 1.4</p>	<p>WARNING</p>  <p>H204</p>
<p>EXTREMELY FLAMMABLE</p>  <p>(R12) (R12) R12</p>	<p>Flammable gases, category 1</p> <p>Flammable aerosols, category 1</p> <p>Flammable liquids, category 1</p>	<p>DANGER</p>  <p>H220 H222 H224</p>
<p>HIGHLY FLAMMABLE</p>  <p>R11 (R11) (R11)</p>	<p>Flammable liquids, category 2</p> <p>Flammable solids, category 1</p> <p>Flammable solids, category 2</p>	<p>WARNING</p>  <p>H225 H228 H228</p>
<p>FLAMMABLE</p> <p>No symbol (R10)</p> <p>No classification</p> <p>flashpoint 56-60°C</p>	<p>Flammable aerosols, category 2</p> <p>Flammable liquids, category 3</p>	<p>WARNING</p>  <p>H223 H226</p>
<p>HIGHLY FLAMMABLE</p>  <p>R17 R17 (R15) (R15) (R15)</p>	<p>Pyrophoric liquids, category 1</p> <p>Pyrophoric solids, category 1</p> <p>Substances/mixtures which in contact with water emit flammable gases, categories 1, 2 and category 3</p>	<p>DANGER</p>  <p>H250 H250 H260 H261 H261</p>
<p>EXTREMELY FLAMMABLE</p>  <p>R12 R12</p>	<p>Self-reactive substances/mixtures, type B</p> <p>Self-reactive substances/mixtures, types C and D and types E and F</p> <p>Self heating substances/mixtures, category 1 and category 2</p>	<p>ING</p>  <p>H241 H242 H242 H251 H252</p>








# Old & New Physical Hazards

Label Elements Old	Hazard Classes and Categories*	Label Elements New**
OXIDISING  R7 R7	Organic peroxides, type B Organic peroxides, types C and D Organic peroxides, types E and F	WARN H241 H242 H242
OXIDISING  R8 R8, R9 R8, R9	Oxidising gases, category 1 Oxidising liquids, categories 1, 2 and category 3 Oxidising solids, categories 1, 2 and category 3	DANGER WARNING  H270 H271, H272 H272 H271, H272 H272
No classification	Gas under pressure - Compressed gas - Liquefied gas - Refrigerated liquefied gas - Dissolved gas	WARNING  H280 H280 H281 H280
No classification	Substances/mixtures corrosive to metals, category 1	WARNING  H290




# Old & New Health Hazards

Label Elements Old	Hazard Classes and Categories*	Label Elements New**
<b>VERY TOXIC</b>  R28 R27 R26	Acute toxicity, categories 1, 2 - Oral - Dermal - Inhalation	<b>DANGER</b>  H300 H310 H330
<b>TOXIC</b>  R25 R24 R23	Acute toxicity, category 3 - Oral - Dermal - Inhalation	<b>DANGER</b>  H301 H311 H331
<b>TOXIC</b>  R46 R45, R49 R60, R61 R39 R48	Germ cell mutagenicity, categories 1A, 1B Carcinogenicity, categories 1A, 1B Reproductive toxicity, categories 1A, 1B STOT***, single exposure, category 1 STOT***, repeated exposure, category 1	<b>DANGER</b>  H340 H350 H360 H370 H372
 R42 R65	Respiratory sensitisation, category 1 Aspiration hazard, category 1	<b>DANGER</b>  H334 H304
<b>HARMFUL</b>  R68 R40 R62, R63 R68 R48	Germ cell mutagenicity, category 2 Carcinogenicity, category 2 Reproductive toxicity, category 2 STOT***, single exposure, category 2 STOT***, repeated exposure, category 2	<b>WARNING</b>  H341 H351 H361 H371 H373
 R22 R21 R20	Acute toxicity, category 4 - Oral - Dermal - Inhalation	<b>WARNING</b>  H302 H312 H332

# Old & New Health Hazards

Label Elements Old	Hazard Classes and Categories*	Label Elements New**
<p><b>CORROSIVE</b></p>  <p>R34, R35</p>	<p>Skin corrosion, categories 1A, 1B, 1C</p>	<p><b>DANGER</b></p>  <p>H314</p>
<p><b>IRRITANT</b></p>  <p>R41</p>	<p>Serious eye damage, category 1</p>	<p><b>DANGER</b></p>  <p>H318</p>
<p><b>IRRITANT</b></p>  <p>R38 R36 R43 R37</p>	<p>Skin irritation, category 2 Eye irritation, category 2 Skin sensitisation, category 1 STOT***, single exposure, category 3 - Respiratory tract irritation</p>	<p><b>WARNING</b></p>  <p>H315 H319 H317 H335</p>
<p>No symbol R67</p>	<p>- Narcotic effects</p>	<p><b>WARNING</b></p>  <p>H336</p>

# Old & New Environmental Hazards

Label Elements Old	Hazard Classes and Categories*	Label Elements New**
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">DANGEROUS FOR THE ENVIRONMENT</p>  <p>R50 R50/53</p>	<p>Hazardous to the aquatic environment, acute, Category 1 Hazardous to the aquatic environment, chronic, Category 1</p>	<p>H400 H410</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">WARNING</p> 
 <p>R51/53</p>	<p>Hazardous to the aquatic environment, chronic, <b>category 2</b></p>	<p>H411</p>
<p>No symbol R52/53 No symbol R53</p>	<p>Hazardous to the aquatic environment, chronic, Category 3/Category 4</p>	<p>No pictogram H412 No pictogram H413</p>

# SDS 16 Point Format

- ❑ Identification of the substance/mixture and of the company/undertaking
- ❑ Hazards Identification
- ❑ Composition/Information on Ingredients
- ❑ First Aid Measures
- ❑ Firefighting Measures
- ❑ Accidental Release Measures
- ❑ Handling and Storage
- ❑ Exposure Controls / Personal Protection

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# SDS 16 Point Format

- ❑ Physical and Chemical Properties
- ❑ Stability and Reactivity
- ❑ Toxicological Information
- ❑ Ecological Information
- ❑ Disposal Considerations
- ❑ Transport Information
- ❑ Regulatory Information
- ❑ Other Information

# SDS Changes

- ❑ Registration number may be included but is not required on GHS SDS, but can be requested from supplier.
- ❑ Email address required in section 1.
- ❑ SDS will make use data present in the Chemical Safety Report.
- ❑ Section 11 – Toxicological Information will become more comprehensive using data generated during registration.
- ❑ Section 15.2 – Indicates if a chemical safety assessment has been conducted by the supplier.